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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CENTER FOR TOBACCO PRODUCTS

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ELECTRONIC CIGARETTES AND THE PUBLIC HEALTH:
A PUBLIC WORKSHOP

+ + +

June 1, 2015
8:00 a.m.

The Marriott Inn and Conference Center
Chesapeake Ballroom Salons A&B
University of Maryland University College (UMUC)
3501 University Blvd. East
Hyattsville, MD 20783

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M E E T I N G

(8:00 a.m.)

DR. DRESLER: All right. Welcome to our third workshop on electronic cigarettes. The first two is, if you've been following it, the first one was on product, science, packaging, labeling; more on the product. The second one was on the individual user, individual health. And this one we'll be looking at the population health, so issues that relate to how electronic cigarettes affect the population. And as you know, the Center for Tobacco Products has a population health standard as we review products.

So welcome to this third session. It is a jam-packed session between today and tomorrow, and so we're very excited to get going.

And with that, let me have Jeannie Limpert come on up.

DR. LIMPERT: Good morning. I'm Dr. Jeannie Limpert from the Center for Tobacco Products Office of Science. I, too, want to welcome you to Day 1 of our third workshop on e-cigarettes.

I would like to spend a few minutes setting the stage and going over some logistical information. The purpose of this workshop and the two previous workshops is to gather scientific

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information and stimulate fact-based discussion about this novel category of tobacco products. This workshop is not intended to inform the Agency's proposed deeming rule. We are not looking for advice or consensus but are interested in an open exchange and discussion of scientific information.

We acknowledge that e-cigarettes present complex regulatory and scientific challenges and that there are strong opinions about these products and their potential impact on the public health. However, we request that all workshop participants be considerate and respectful of all other participants, the information being presented, and the opinions expressed by others.

We have asked all speakers and panelists to voluntarily disclose any financial interests and relationships that they may have in e-cigarettes, electronic nicotine delivery systems, or any other relevant products or companies.

As Carolyn mentioned, the focus of this two-day workshop is the population health effects of e-cigarette use, including the health effects of e-cigarettes in nonusers.

Today we will have four sessions. Each session will consist of a series of presentations followed by clarifying questions and a panel discussion. The four sessions today

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include: Prevalence and Patterns of Use; Reasons for Use, Flavor, and Product Appeal; Marketing; and Knowledge, Attitudes, and Beliefs.

Our agenda today is very full, and so presenters have been asked to keep their presentations within the time period allotted, and a timer will be used in order to stay on schedule.

We will have two 15-minute breaks, an hour for lunch, and end the day at 5:00 p.m. Please remember to bring all personal items with you when you leave the room.

A note for tomorrow: We will start the day at 8:00 a.m. with the public comment session. The time for this session is based on the number of registered speakers. If some of the registered speakers do not show, the day's schedule may be adjusted accordingly and we may run ahead of schedule.

For those who have a clarifying question for a speaker or a question for the panel, if you are here on site, please write your question on one of the cards provided using legible handwriting and give the card to one of our volunteers. If you are participating by webcast, you can e-mail your questions to the workshop e-mail address, which is workshop.ctpos@fda.hhs.gov.

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Please write on the card whether the question is clarifying and, if so, for which speaker, or whether the question is for the panel. Please ensure that your card actually includes a question. We will try to get to all the questions but may not be able to do so due to time limitations. We will try to combine related questions to avoid duplication.

The workshop is being recorded. The transcript and webcast recordings will be posted on our website in approximately 1 month.

The restrooms can be found outside of this room in either direction down the hallway.

Lunch options today include an Italian buffet lunch in Patuxent Room 2. The cost for purchasing lunch is \$14.00. There's also a restaurant located in the lobby.

We request you refrain from use of all tobacco products, including e-cigarettes and other electronic nicotine delivery systems, during the meeting.

Please note that for any media inquiries, Michael Felberbaum is our press contact.

Michael? He's in the back of the room. Thanks.

I would now like to turn the podium over to the workshop moderator, Dr. Carolyn Dresler.

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DR. DRESLER: Okay. And so as she said, we're going to try and really stay on time, and for those of you that come at the end of the day, you'll really appreciate it if I do a good job with that. So if you see these lights going on and the yellow one, and then the red one means I will be standing up and doing increasingly hinting behaviors, even though I will be sitting over here. So with that, please do try and stay on time thinking of your fellow speakers that will follow you.

Okay, so our first session is Prevalence and Patterns of Use, and our first speaker is Brian King. Dr. King is from the Centers for Disease Control and Prevention. He will be speaking on Patterns and Correlates of E-cigarette Use among U.S. Adults from the National Surveillance Data.

Brian.

DR. KING: Wonderful, thank you. I'm very pleased to be here today and first on the docket, no less. It can only go uphill from here, I imagine.

So today, before I start, here's my funding and disclosure. As you're already aware, I am an employee of the U.S. Federal Government; depending on who you ask, that could or could not be a conflict of interest, but here we go. No conflicts of interest or funding sources to declare. And also

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give the caveat that the findings and conclusions I'm presenting here today are not the official position of the U.S. Centers for Disease Control and Prevention.

So this is not intended to be an eye exam. I apologize if this is difficult to see from afar, but I'm just going to briefly overview the CDC surveillance systems that actually assess electronic nicotine delivery systems and have measures. I'm going to be talking about two of them primarily today. This is just a brief background of the mode, periodicity, scope, population, sample, and response rate for those surveys.

The two I'm going to be talking about today are the HealthStyles survey, which is an Internet panel survey that has been conducted for many years. And we first added questions among adults in 2009, a very limited sample, so we have sufficient samples from 2010 forward, and that's annual, conducted in the summer, about 4,000 respondents and a 65% response rate.

The other is the National Adult Tobacco Survey, which CDC initiated in 2009-2010. It did not include ENDS measures at that time, but it was re-fielded in 2012-13 and 13-14 in collaboration with FDA, and we do have e-cigarette measures on both of those. And it's about 60,000 adults, a random digit

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dial phone-based survey, landline and cell phone.

And so in terms of the timeline of ENDS surveillance systems, I've already gone into this a little bit in the preceding slide, but we started conducting surveillance of e-cigarettes at CDC back in 2009, and since then we've really expanded. CDC is doing the bulk of the surveillance in this area. But that is just CDC surveillance measures that I presented.

In terms of measures, this is what we're currently assessing. There is certainly opportunity to expand those in the future, but the ones that I'm going to be focusing on today in terms of findings are, again, the HealthStyles and the National Adult Tobacco Survey 2012-2013 and indicators of awareness, ever use, and current use. And those are the primary focus of today. But the bulk of these data are also available publicly for some of these other surveillance systems.

So we'll just start with some brief data on awareness, and as we can see, we've seen marked increases from the HealthStyles survey in terms of awareness among U.S. adults. In 2010 we were looking about 2 in 5 adults, and now we're at 4 in 5, and the 2014 data are showing even greater levels of

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awareness. The vast majority of adults have now heard of these products.

In terms of ever use of the products, this is trend over time, and please note that this ever use measure can include the variety of users. So this could be people who use the product just one time and then never used it again and also the more recent users, the current users as well. So you can see back in 2010 there was about 3.3% of U.S. adults age 18 and over had ever used these products at least once. And between 2012 and 2013, there was not a change, about 8%, 8.5% in 2013. And we do have the 2014 data, and we expect increases moving forward with future iterations of the survey.

Now, this is just a brief overview of past 30-day use, and this is our measure of current use, so again that caveat. This is used on at least 1 day in the past 30 days, so you could potentially include people who have used it just 1 day in the past 30, as well as those who have used it all 30 days. And it looks like my Mac has caused some issues with that 2010 value; it didn't translate forward, but it's 1% in 2010. So there was no statistically significant change between 2010 and 2012, but we did see an uptick in 2013 to about 2.6% of adults had used these in the past 30 days, and again, in 2014 the most recent

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data do show increases as well.

So now, more importantly is the stratification by different population subgroups, the most notable of which is cigarette-smoking status. So this shows stratification by cigarette-smoking status. You have your current, former, and never cigarette smokers and trends over time. You can see the definitions of those at the bottom. These are the standard definitions we use to define current smoking from the National Health Interview Survey. So it's at 100 lifetime use measure, and then do they now, at the time of survey, use cigarettes every day, some days, or not at all. So you can see that we've seen marked increases from 2010 to '13, most notably among current cigarette smokers and former cigarette smokers. Of course, these are cross-sectional data, so we can't ascertain temporality of when they use the respective products. And in terms of never cigarette smokers, it has remained fairly unchanged among adults, around 1% over time over this period.

So now here's some further stratification by the proportion of current cigarette smokers among adult ever e-cigarette users. So those who have ever used the e-cigarette is the denominator, and you can see, again, about two-thirds are currently smoking cigarettes.

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And here's the proportion of never cigarette smokers among U.S. adult ever e-cigarette users, so those who have ever used the products that have never used a conventional cigarette. This has fluctuated with year, but the sample is quite small, so that's the caveat here, that there's not necessarily statistically significant changes over time. But most recently, in 2013, about 8.7% of ever e-cigarette users had never used a conventional cigarette.

And so now here's the current measures of currently using both products. And, again, this is the past 30-day, and remember that definition of cigarette smoking is slightly different. It's that ever use threshold, 100 in their lifetime and then every day or some days, and then the e-cigarette is past 30 days, so slight difference in your definition of current. And we aggregated years here because of sample, but you can still get the general gist. It's comparable to what we're seeing in the ever use measure. So, in terms of the current use of both products, it's about 9.4% of current cigarette smokers, 1.3% of former cigarette smokers, and 1% of never cigarette smokers in 2012-13. And looking at the 2014 data moving forward, we expect those increases to follow similar patterns.

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So now here is the proportion of current cigarette smokers among U.S. adults who used e-cigarettes within the past 30 days, so this is the flipped current e-cigarette users are your denominator. And what we see here is that the vast majority of current e-cigarette users are also using conventional cigarettes, close to three-quarters, in 2012-2013. We do not expect that to change in 2014. Moving forward, we'll have sufficient sample now that the use is getting high enough that we can do annual estimates over time.

So now moving into more of the correlates of use, and these are from the National Adult Tobacco Survey 2012-2013. These were published by CDC and FDA in the *Morbidity and Mortality Weekly Report* last year. And remember, 60,000 adults completed the survey, so we have sufficient sample to really tease out among some of these demographic groups, at least at the overall level, not necessarily teasing out any more nuance than that.

One interesting indicator that we included was an every day/some day measure which we typically do with conventionals, but also a rarely option. And that was the first year that we did that, and we included it for the e-cigarette measure. And so the subsequent slides that I'm presenting are going to show

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you just the every day/some day responses in blue, but also those who responded rarely. And what you're going to see is that there are marked increases in the proportion of current use if you include those respondents who reported rarely.

Now, of course, we're not necessarily sure what exactly those rarely users, you know, how frequently they've used them or what exactly the definition of rarely use is to them, it can be quite subjective, but we do know that the people selecting that response option considerably increases the prevalence of current use.

And so this is the overall measure, and as well as by sex, and you can see slightly higher among men compared to women and about 2% overall for every day/some day, but nearly twofold higher when you include that rarely response option.

These are the differences by age, so you can see slightly graded as you go down in terms of age, which is comparable to what we see with conventional cigarette smoking. The prevalence of current use of e-cigarettes is higher among the younger adult demographics; it was about 8.3% for the every day/some day/rarely measure in 2012-2013.

These are our findings in terms of race/ethnicity. Not quite a bit of variation other than the other non-Hispanic

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demographic. We do have some limited cell sizes for certain populations such as Asians where we can't get reliable estimates. But, overall, you see that there is some variability. Not necessarily consistent with what we see with conventional tobacco products, particularly with regard to the non-Hispanic white and black populations, not necessarily a similar pattern.

These are the findings by education. And these are comparable to what we see with conventionals, typically increased education is lower prevalence of use of these products. It's highest among those with a GED, about 8.1% for the every day/some day/rarely measure and down to slightly less than 1% for those with a graduate degree.

Here's the stratification by annual household income. And this does not -- a lot of variability, but a slightly lower prevalence among those who make over \$100,000, but no statistically significant differences among those. Less than \$20,000; \$20,000-\$49,000; or \$50,000 to slightly less than \$100,000.

And these are our findings by region. Most remarkably, out of all the covariates that we've assessed, region is the one where there is no statistically different findings across

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the four major U.S. census regions, and that has been fairly consistent over time. We've also seen that in HealthStyles. No marked variation overall by the four major U.S. regions.

And here is by sexual orientation. It looks like we might be having some slide issues, but I will walk you through it. So, essentially, what we are seeing is a higher prevalence among the lesbian, gay, and bisexual communities. We do not include a transgender measure in the National Adult Tobacco Survey, so it's just LGB, but we can see markedly higher prevalence use of e-cigarettes among this population, whether you account for the every day/some day or also you include the rarely measure.

And here's just a brief schematic of the frequency of use. This was published in the *Morbidity and Mortality Weekly Report*, and this is among ever users of the product. So, for e-cigarettes, our threshold is they used it at least one time in their life. So this is a true ever use measure. And then it's the frequency of how frequently they use it now. So not at all, rarely, some days, every day. So you can -- this shaded box here is for e-cigarettes.

And so among ever e-cigarette users, about 75% do not use the products currently at the time of survey. About 15%

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reported using them rarely at the time of survey. About 10% used them some days. And then 5% of ever e-cigarette users reported that they currently use the products every day at the time of survey. So at the current point, this is the best that we can do in terms of the frequency measure among adults from the National Adult Tobacco Survey, but we have included more nuance indicators in the 2013-2014 survey where hopefully we'll be able to get into a little bit more specific data and we'll have sufficient sample to adequately address that now that we have higher prevalence of use over time.

And so in terms of just summary, key takeaway points from these findings from CDC:

The use of e-cigarettes has increased among U.S. adults in recent years going back to 2010 when we have data. This increase has primarily been driven among current and former cigarette smokers.

We've seen most past 30-day e-cigarette users are also using current cigarettes. They're also currently using cigarettes, so that's what we call dual use.

And there are variations in current e-cigarette use across most indicators. The U.S. region is the only one where we haven't seen those variations, but for the most part, these

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differences across strata are comparable to what we see with conventional cigarettes.

And also, important to note from a methodological standpoint, is accounting for occasional or rarely e-cigarette use can actually significantly impact estimates of current use. So we have included this rarely measure in future iterations of the National Adult Tobacco Survey, and there's also some other surveys at the national surveillance level that are also considering this, and we're working to tease out what exactly those rarely users are and how they interpret their use by comparing it to other levels of frequency, such as a past 30-day measure.

And with that, I will end with my contact information. All of the information I've provided to you today is publicly accessible by peer review publication or *Morbidity and Mortality Weekly Report*, and the datasets for the National Adult Tobacco Survey are also available publicly online through 2012-13. The HealthStyles survey is actually run by Porter Novelli. CDC does not own those data, so we cannot publicly release them. But they are accessible, the findings, from publications. And with that, you can feel free to follow up through this resource for any other information on the data I

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presented for you today or any of the other surveillance systems.

Thank you.

(Applause.)

DR. DRESLER: Thank you.

Our next speaker is Dr. Richard Miech from the University of Michigan speaking on Drug Use Patterns of Adolescent E-cigarette Users.

DR. MIECH: Well, I'd like to thank the organizers for the opportunity to present my research. That's a hard act to follow. I'll do my best. I'm going to focus on -- hello? Okay.

(Microphone malfunction.)

(Pause.)

DR. MIECH: Hello? Okay, great.

Okay, so I'm focusing on adolescents, which is a younger age population than what we saw in the previous presentation. And it's been in the news lately, adolescent e-cigarette use has increased rapidly. 2014, in our data, which I'll talk a little bit more, Monitoring the Future, we found that in 2014 the prevalence of past 30-day e-cigarette use was 9% among 8th graders, 16% among 10th graders, and 17% among 12th graders.

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And there's going to be a quiz on that at the end of this presentation about those numbers, all right; 9, 16, and 17 percent.

So this is a very rapid rise in prevalence. The estimated prevalence, according to the CDC, in 2011 was 1%, so the popularity among adolescents has really been increasing rapidly. And Monitoring the Future just asked about e-cigarettes for the first time in 2014. Of course, the CDC has asked about it for a longer period of time, and according to their findings, they also find that there has been a substantial increase in adolescent e-cigarette use. And they report a tripling of use from their previous assessment in 2013. And e-cigarettes are now more popular than regular cigarettes among youth. In 8th and 10th grade, e-cigarette prevalence is twice, more than twice that, of regular cigarette use.

So not a lot of information is out there yet because e-cigarettes are so new and much remains unknown about these young e-cigarette users. And what I want to focus on now is their pattern of use of other traditional drugs of abuse. Monitoring the Future can kind of flesh out some of the existing research here. It's one of the few studies that goes

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into a lot of detail about other drugs like marijuana, binge drinking, prescription drug use, and what have you, and we can look at e-cigarette use among adolescents in relation to these other drugs. So the question I'm focusing on here is are these adolescents who "were going to use drugs anyway"? And by that, what I mean is that every study that looks at drug use among adolescents finds that there's a group of people, a group of kids, who just really like to use drugs and they use all kinds of drugs. And these adolescents who have a proclivity for drug use, have they just adopted e-cigarettes into their drug repertoire?

Okay. So my formal research question is: Are e-cigarette users who are adolescents, are they polysubstance users who are likely to abuse a wide range of substances? Or yeah, so is it just an expansion of their repertoire? They were going to use lots of drugs anyway and they've incorporated e-cigarettes into their patterns of use. Or instead, are e-cigarette users youth who do not typically use traditional drugs of abuse? This could potentially represent new recruits to substance use if e-cigarette users come from the pool of people who do not typically use drugs.

So the data for this study come from Monitoring the

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Future. It's an ongoing series of surveys of American adolescents, college students, and adults conducted by the University of Michigan at the Institute for Social Research. It's funded by the National Institute on Drug Abuse, and it's renewed every 5 years; for the past 40 years it has been. It's a competitive process to get funding for it.

So every year we draw a nationally representative sample of 8th, 10th, and 12th graders, approximately 40,000 students in all. And we have different forms, so not all of the adolescents get the same survey, and that allows us to ask questions about a wide variety of drugs. And some of the forms include questions on e-cigarettes in 2014. And as a result of that, in 8th grade we have about 4,000 8th graders who were asked about e-cigarettes. In 10th grade, we again have about 4,000. And in 12th grade we have about 8,000 adolescents who were asked about e-cigarette use.

So what do we expect to find? Well, the current literature on adolescents suggest that e-cigarette users could fall into the following classes: They could be polysubstance users; every study of adolescents that's representative of a population finds that there's a group that is a polysubstance using group. I also expect to find there's going to be a low

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level or non-using group; this is typically the largest group, thankfully, in studies of adolescents. So e-cigarette users could fall into either one of those two groups. They could be part of the polysubstance use group, or they could be part of the group that doesn't really use any drugs at all. These results may vary by age, so I separate the analysis, and I'll show you the analysis for 8th graders, 10th graders, and 12th graders to see if there's any differences developmentally.

What I'm going to show you, first, are descriptive statistics of e-cigarette use by demographic groups, simple descriptive statistics. And then I'm going to present results from a latent class analysis that includes e-cigarettes with traditional drugs of abuse. So latent class analysis is a fancy name, but basically what it wants to do is it looks for groups in the data, what are the major groups. So if you are marketing, there's segmentation analysis; conceptually, it's similar to that. Latent class analysis will tell us not only what the major groups are, but how many groups there are. So if you're familiar with factor analysis, it will tell you if the best-fitting model is two groups of drug users or three or four. And I'm going to look at e-cigarette use in relation to the most common drugs that are out there that are used by

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adolescents, so that's marijuana, traditional tobacco cigarettes, binge drinking, and prescription drug abuse.

And just to tell you where this falls, the contribution of this study, to my knowledge, no one has yet looked at e-cigarettes in a latent class analysis in terms of its grouping with major drugs of abuse. And also to my knowledge, nobody has looked at this type of question focusing on specific grade, you know, at 8th, 10th, and 12th grade, and paid particular attention to potential differences in the results depending on the specific grade that you're focusing on.

Okay, so the results. The first, I'm going to look at 30-day e-cigarette prevalence, so have they used e-cigarettes in the past 30 days. By sex, what we find is that -- these are males here. In 8th grade, males have slightly higher prevalence, almost 10%, than females. In 10th grade, again, males have higher rates or higher prevalence, I should say. And in 12th grade, they also have higher prevalence. So that's a common finding among drug use among adolescents.

We look at e-cigarette use in the past 30 days by parents' education. And it turns out if you just focus on parents with a college degree and parents without a college degree, the adolescents who have parents without a college degree have

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higher rates or, I'm sorry, higher prevalence of e-cigarette use in the past 30 days. And you find this in 8th grade, you find it in 10th grade, and you find it in 12th grade.

And if you look at college plans, we asked adolescents, do you plan to go to college? The adolescents who say they don't plan to go to college are much more likely to use e-cigarettes than those who plan to go to college.

Finally, race/ethnicity. What we see is that Hispanics in 8th grade seem to have the highest prevalence. And one of the most common findings here is that black or African-American adolescents have the lowest rates of e-cigarette use, which is a common finding also in adolescent drug abuse, that African Americans, for most substances, have the lowest rates or lowest prevalence of drug use.

Okay. So now I'm going to zero in on clusters of substance use, results from my latent class analysis. And what I found was that in 8th grade there are two major groups of drug users. So what we have here on the right is the polysubstance using group. So this is about 9% of the population, and what you find is that people who are in this group, 8th graders who are in this group, they have a high probability of using every drug that we measured here. So they

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have about a 50% chance of using e-cigarettes in the past 30 days, about the same probability of using a cigarette, same probability of binge drinking. Marijuana use is slightly higher in terms of its probability. And they also have significant probability of using prescription drugs. And over here we have 91% of our 8th graders, and what we find is they have a pretty low probability of using all drugs. And this is consistent with previous findings in the literature in terms of there are two major groups for this age range.

Now, what's important to note here is that this group here is 9% of the population, and they have about a 50% chance of using e-cigarettes in the past 30 days. So if the total population is 9% and they have a 50% chance, that means -- you multiply 50% times 9%, that means about 4.5 out of every 100 8th graders who use e-cigarettes come from this group.

Now, here's the quiz. Do you guys remember the prevalence of e-cigarette use among 8th graders? Nine percent, right? So 4.5 of every 100 come from this group and the other 4.5, the other 50% of the total 9% population, come from this group here. So these findings show that in 8th grade, the e-cigarette users, about half of them, come from the polysubstance using class, and the other half come from the

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group that traditionally don't really use any drugs at all.

Okay, so moving on to 10th grade, we see that the polysubstance using class is 18% of the 10th grade population. This is expected. The polysubstance use class tends to grow as kids get older. And then we have the low-level cigarette users here in 10th grade, it's about 82%. And I'm going to do the math for you here.

Remember the prevalence at this particular age level of e-cigarette use in the past 30 days was 16%, and if this is about this group here, the polysubstance use, if you're a polysubstance user, you have about a 60% chance of using an e-cigarette in the past 30 days. And this is 18% of the population. So 60% of 18 is about 10 or so and -- well, I'll present the math a little bit later. But it turns out that in this group, whereas before we saw that about half of the e-cigarette users came from the polysubstance use group, in 10th grade 65% of e-cigarette users come from the polysubstance use group, and 35% come from the group that don't usually use cigarettes or any drugs that much.

So then I'm going to go to 12th grade next, and the latent class analysis shows that there's actually three major groups that best fit the data. And what we see is our usual

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polysubstance group over here, which is about the same size as it was in 10th grade, about 17% of the population. We have a smaller group that are defined by predominant e-cigarette use, so they have a very high probability of using e-cigarettes, and they also are polysubstance users because they also have substantial probability of cigarette use, binge drinking, and marijuana use. And then over here we have our typical group that has a very low probability of using any substances. And the big point here is that among these two polysubstance groups, they account for about 90% of all e-cigarette users in 12th grade. And over here we have about 10%, actually, 12%.

And so to summarize all that, in 8th grade the percentage of e-cigarette users who come from the polysubstance using group is 50%. By 10th grade it becomes 65%, and by 12th grade it becomes 88%. And alternatively, the percentage of e-cigarette users who are coming from this group that don't usually use drugs declines with age. It was 50% in 8th grade, 35% in 10th grade, and 12% in 12th grade.

So summary: Adolescent e-cigarette users are more likely to be males, from lower socioeconomic backgrounds, without plans to go on to college.

E-cigarette users come both from the pool of adolescents

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who do not use traditional drugs of abuse, as well as from the pool of polysubstance users.

The proportion of e-cigarette users who are polysubstance users increases with advancing age: in 8th grade, about half of e-cigarette users come from the pool of youth who do not use traditional drugs of abuse, whereas in older grades, practically all e-cigarette users are also using other drugs. So among 12th graders, at least, it looks like e-cigarettes are supplementing and not substituting for use of traditional drugs.

National longitudinal studies, such as the PATH study, I want to emphasize the importance of that study, will be able to determine if the changes in e-cigarette drug using profiles with advancing age represented we could have, but the same adolescents in 8th or 10th grade, they could be becoming polysubstance users, or it could be that different groups of adolescents are moving in and out of drug use. So the reason for these findings could be that maybe the 8th and 10th graders who are using e-cigarettes, maybe they stopped and new adolescents came in, in 12th grade who are just using all these types of drugs. And a longitudinal study will really be one of the best to determine which of these two competing

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interpretations is correct.

That's it.

(Applause.)

DR. DRESLER: All righty.

Okay, our next speaker is Dr. Lauren McCarl Dutra from the University of California, San Francisco, and she will be presenting Adolescent E-cigarette Use: What We Already Know.

DR. DUTRA: Good morning. My name is Lauren Dutra. I'm here from the Center for Tobacco Control Research and Education at UCSF. And I'll be talking to you -- is it cutting out again? I'll be talking to you about what we already know about adolescent e-cigarette use.

I don't have any conflicts of interest. My research is funded by the National Institutes of Health, and I've never received any funding that was either pro or anti e-cigarette.

The e-cigarette industry has been sending the message that we really don't know anything about e-cigarettes at all and therefore we can't really make any decisions about them. So I'm here to tell you what we already know.

Am I cutting out?

UNIDENTIFIED SPEAKER: Yeah.

DR. DUTRA: Yeah, okay.

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(Pause.)

DR. DUTRA: Okay, thank you.

Marketing for e-cigarettes is out of control, and it appeals to youth; e-cigarettes are expanding nicotine use among adolescents; they're associated with more progression to established smoking among kids; and less former smoking in kids; and less quitting in adults. This is the current environment that we're dealing with right now from marketing, which you'll hear a lot more about later today.

And we see very in-your-face ads that sell sex and appeal to youth, as well as marketing techniques like these Hello Kitty drip tips that use cartoons to appeal to youth, something that we're not used to having seen for quite some time.

E-cigarettes are available in a wide variety of kid-friendly flavors like cotton candy and candy cane. And when I say marketing's out of control, I'm talking about rapidly increasing use, but also the fact that this is something that, you know, isn't regulated in the way that cigarette marketing is regulated.

So focusing your attention on the far right-hand column, you'll see this data from RTI. 2011 is represented in blue, and yellow represents 2014 data. You can see that e-cigarette

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advertising expenditure has rapidly increased from \$6 million in 2011 to over \$100 million in 2014. And in combination with data from Duke and colleagues, we know that these increasing advertising expenditures have directly translated to increased youth exposure to these ads, which in turn increases the likelihood that kids will try these products.

And, in fact, that's what we're seeing: rapidly increasing e-cigarette use among kids. This is current or 30-day prevalence of e-cigarette use among kids in the National Youth Tobacco Survey from the CDC, and what they found was that among middle schoolers -- sorry, middle and high school students all over the United States, e-cigarette use doubled between 2011 and 2012, and then in turn tripled between 2013 and 2014. In fact, according to the Monitoring the Future study, which is also a large representative study of the entire United States, we also see that current use or 30-day prevalence for e-cigarettes has now exceeded cigarettes.

So what about overall nicotine consumption? One thing that we have to do is we have to separate out the dual users. We don't want to count them twice in our calculations of overall use of both cigarettes and e-cigarettes.

So I've taken data from the California Healthy Kids

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Survey, which is a sample of over 10,000 7th, 9th, and 11th graders, and I've mapped ever smoking first in blue from 2003 to the most recent wave of data collection in 2013-2014. In the most recent wave of data collection, the CHKS actually added a question about e-cigarette use which allows us to look at e-cigarette use in the context of smoking, as well as to separate out these different groups of users. So as you can see on the right-hand side, cigarette only users are represented in black. Dual users of cigarettes and e-cigarettes are represented in red. And e-cigarette only users are represented in yellow. And the reason that I picked ever use for this graph is because I want to make the point that this data directly contradicts the argument that only smokers are using e-cigarettes. You can see here the kids who are using e-cigarettes, so that's the red and the yellow bars, that over half of them are only using e-cigarettes, they've never tried a cigarette.

And you can see, in comparison to when e-cigarettes entered the U.S. market in around 2007, our total nicotine consumption from cigarettes and e-cigarettes is actually higher in 2013. And I just want to give you an idea of the age of these kids that we're talking about for 7th graders. This is

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what a 7th grader looks like. These kids are really young.

This is the same graph for 9th graders. We see, once again, a very similar pattern. We see that over half of the e-cigarette users are only using e-cigarettes; they've never tried a cigarette. And we also see that overall nicotine use from cigarettes and e-cigarettes is up. It's higher than it was before e-cigarettes entered the market in the U.S.

Once again, we have similar results for the 11th graders in the sample. We see that overall nicotine use is high; it's actually higher than it was before e-cigarettes entered the U.S. market.

This pattern is consistent with the pattern we're seeing on an international level. This is a chart that represents the percentage of never smoking among e-cigarette users. So taking all of the kids who have ever used e-cigarettes, we looked at what percentage of them are never smokers, what percentage have never tried a cigarette. And these are middle and high school students. So, for the United States, for Korea, Paris, Germany, and Poland, we see that a substantial portion of e-cigarette using adolescents have never smoked a cigarette.

So the question is are kids initiating nicotine with e-cigarettes? And that's a trickier question. Data from

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Connecticut middle and high school students show that among ever e-cigarette users -- so they took the kids who had ever tried e-cigarettes, and they asked them what's the first tobacco product you ever tried. Fifty-one percent of middle school e-cigarette users said an e-cigarette was the first tobacco product I ever tried. Nineteen percent of high school e-cigarette users said e-cigarettes were the first tobacco product I ever tried. And then they just asked the kids who had never tried a cigarette but were current e-cigarette users, so they'd used cigarettes in -- sorry. They used e-cigarettes in the past 30 days. Twenty-five percent of them said they started out with a nicotine-free e-cigarette, that was the first one they tried, but they were currently using nicotine-containing e-cigarettes.

So why do we care so much about nicotine? Well, the 2014 Surgeon General's report tells us that nicotine itself is a harmful addictive product, and it affects not only cardiovascular health but also the immune system. A recent paper by Lucy England and colleagues talked about the effects of nicotine on the developing brain, which we know affects memory and concentration in adolescents and according to animal models basically rewires the brain.

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So what does the tobacco industry have to say about nicotine? In 1992 an internal Philip Morris document said this: People smoke cigarettes for different reasons but primarily to deliver nicotine into their bodies. And they compared nicotine to similar organic chemicals like quinine, cocaine, atropine, and morphine, noting that nicotine had a particularly broad range of influence on human physiology. So we know the tobacco industry has known about the effects of nicotine for at least the past 20 years. Actually, it's 50. Brown and Williamson, in a 1963 internal document -- actually, their general counsel and vice president at the time said this about nicotine: Nicotine is addictive, and we are in the business of selling nicotine, an addictive drug.

So the next question you asked is would these e-cigarette users have smoked anyway? A recent study by Wills and colleagues in Hawaii looked at this question, and they looked at a variety of risk factors that are traditionally associated with cigarette use. And they had some interesting and tricky findings.

So they found that e-cigarette only users were a lower risk group than the kids who are smoking cigarettes, whether that was dual use of cigarettes and e-cigarettes or kids who

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are using cigarettes only. In addition, they did score low on some smoking risk factors that are traditionally associated with cigarette smoking, like rebelliousness, sensation seeking, and peer smoking. So this data really calls into question are these kids a unique group of users, and would they have used cigarettes anyway?

So what's going to happen in the future? Will e-cigarette users smoke in the future? Combining data from several studies, we see that ever e-cigarette users are more likely to intend to smoke, and this is, once again, adolescents. They're also more open to smoking in the future.

I analyzed data from the National Youth Tobacco Survey, which is put out by the CDC, and looked at the relationship between e-cigarette use and cigarette smoking among kids. So first I concentrated just on the kids who had ever experimented with cigarettes, so they had at least a puff of a cigarette. And what I saw is that the ever e-cigarette users were more likely to be established smokers. They were more likely to have already smoked 100 cigarettes or more.

In fact, they were six times as likely to have become established smokers as opposed to continuing to experiment with cigarettes than the kids who had never smoked an e-cigarette.

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They were also more likely to be current smokers, to have used cigarettes in the past 30 days, over 5½ times as likely. And the results were similar for current e-cigarette use.

So then I looked at the kids who were already established smokers, the kids who had already smoked 100, over 100 cigarettes in their lifetime. And I found that ever e-cigarette users were less likely to be former smokers. In fact, these kids were 70% less likely to say I haven't smoked a cigarette in the past year. And these findings were similar for current e-cigarette use.

So we definitely need longitudinal data on adolescents, but we know that nicotine use is increasing and nicotine is an addictive and toxic drug. Dual use of cigarettes and e-cigarettes is high. Kids who are at low risk of smoking are initiating nicotine with e-cigarettes, and e-cigarettes are suppressing former smoking.

So what about e-cigarette use and quitting in adults? Well, we do have longitudinal data for this and this data is based on actual use patterns.

Some of my colleagues at UCSF did a meta-analysis of all of the cohort studies that have been done of adults looking at e-cigarettes and smoking cessation. And what they found is

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that the people who used e-cigarettes were actually 30% less likely to have quit smoking.

So this is what we already know about e-cigarettes and kids:

- Marketing is out of control.
- E-cigarettes are expanding nicotine use.
- They're associated with more progression to establish smoking among kids.
- Less former smoking in kids and less quitting in adults.

Thank you.

(Applause.)

DR. DRESLER: Okay, our next speaker is -- he's on the phone? So he's going to present via the phone? All right.

(Laughter.)

DR. DRESLER: Will he have a microphone that works? Yes? No? Are we ready? Okay.

So our next speaker is Dr. Geoffrey Curtin from RAI Services Company, and he will be speaking on Tobacco Use Behaviors among Adult E-cigarette Users. And I think the reason he was unable to be here was airplane issues, right? So he wanted to be here but -- so here he goes. Ready?

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Dr. Curtin, are you on the phone?

DR. CURTIN: I am on the phone. Can you all hear me?

DR. DRESLER: Yes, well.

DR. CURTIN: Very good. So I appreciate the opportunity to speak this morning. You all have been far more accommodating than the airlines were yesterday, no doubt. And I'm sorry there's a delay in what I'm seeing on the screen. So are we ready to go?

DR. DRESLER: Yes.

DR. CURTIN: Hello?

DR. DRESLER: Yes, we are.

DR. CURTIN: Oh, okay. Very good.

My name is Geoff Curtin. I'm a Senior Director with Regulatory Oversight group at RAI Services, and I'd like to speak to you today about tobacco use behaviors among adult e-cigarette users.

So I see the second slide is up.

The behavioral outcomes of interest, I'll be speaking to you about, again, among U.S. adults. Prevalence of e-cigarette use. Cigarette use among e-cigarette users. We've developed a number of tools here at RAIS which allows us to look at things that haven't been reported much in the literature, and that is

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product order and directionality among e-cigarette users who ever used traditional cigarettes. And we'll be looking at cigarette quitting among e-cigarette users who have used cigarettes prior to e-cigarettes. And then an issue that's of importance, cigarette initiation or gateway among e-cigarette users.

Next slide, please.

So we've developed a number of survey tools which allow us to look at tobacco use behaviors. The first one I'll talk about is the National Tobacco Behavior Monitor. This survey was kicked off in May of 2010. It is a rolling monthly cross-sectional survey that talks to about 2,000 respondents per month. It is a survey that tracks adult tobacco use behaviors by product, brand, and style. So, in many cases, it's a postmarket surveillance survey. There is an emphasis on initiation, cessation, and recidivism.

And we look at behaviors across 20 different tobacco categories, everything from cigarettes to NRTs, and smokeless tobacco products are broken down more granularly as are cigarettes and e-cigarettes are as well. The samples drawn from online panels, a series of online panels that are weighted to U.S. census data, again, the data are collected monthly,

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about 2,000 respondents per month. So at present we have about 130,000 people in our database, and we added the e-cigarette questions in January of 2013, so I'll be presenting about 24 months of data from the NTBM. We took a look at the KnowledgePanel, GfK's KnowledgePanel at the end of 2013 and actually incorporated that into our survey beginning of 2014 that adds another 500 respondents. The GfK KnowledgePanel is an online probability sample representative of the U.S. adult population, and it recruits and employs an address-based sample frame, so people that wouldn't have access to computers or Internet, that access is provided.

Next slide, please.

So the second survey I'll talk about is the Total Tobacco Migration Tracker, which started a little earlier in 2008. It is really a tobacco harm reduction survey in that it assesses tobacco adult -- I'm sorry, adult tobacco users' attitudes, behaviors, and understanding of the total tobacco category, again, based on 20 different product categories. The emphasis is on risk perceptions and tobacco use patterns. We look at prevalence of use, product switching and quitting, dependence.

And importantly, for both of these surveys, we ask retrospective questions so we know when people initiated with

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product, what age, what product they initiated with, and what product they went to later on. For this particular survey, we ask a series of questions, first product, second product, third product, so we really can look at the total tobacco journey. Much like the last survey, it's drawn from online panels weighted to the U.S. census, and the data are collected monthly, but there was a period from 2010 to 2014 where we only collected data during the first quarter, so January, February, and March. Much like the other survey, the e-cigarette questions were added in January of 2013.

Next slide, please.

So first question: Prevalence of regular e-cigarette use among U.S. adults. The way these slides are laid out is the top line of data will be from NTBM, again a 24-month period from January 2013 to December 2014. Population size is about 51,000. And the first or center column will be current regular e-cigarette use, and to the right of that will be ever regular e-cigarette use. We defined current regular use as having used product on 10 of the last 30 days. For evers, it would be having used a particular product 10 days on any 30-month period.

And while we have the ability to do this in both surveys,

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the second dataset from the Total Tobacco Migration Tracker, TTM, will be based on self-defined current or ever regular use. We see good concordance across these measures, and it's also important to mention that because of the questions we ask, we could look at past month use, any past month use, even one time, as we see a lot of in the literature.

We can define regular use as 10 days, 20 days, and we can also look at daily use. So we have all that latitude within these surveys. But based on this first dataset, the prevalence of current regular e-cigarette use among U.S. adults is estimated to be about 5 to 6%, whether we define them based on some or all days or 10 days in the last 30 or we'll allow them to self-define. Ever regular use is a little higher, between 9 and 10%.

Next slide, please.

Again, this is a rolling cross-sectional survey, so we can look at trends. The solid green line at the bottom of the page is adult current regular use of e-cigarettes, and we go from about 2.6% in the first quarter of 2013 to about 6.5% in December or the fourth quarter of 2014. We can also break down by age demographics. The smaller dash line is e-cigarette users 18 to 24 years. You see that that number, like the

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e-cigarette overall number, has statistically increased. It somewhat reflects the overall count. We see our greatest prevalence in ages 25 to 44 years, where the prevalence is 3.5%, and it increased more dramatically up to 9.4% in any of the other age demographics. The older age demographics are below the solid line and are not shown. At the same time we see -- we can look at cigarette prevalence as well. And cigarette prevalence has declined over that same period but not statistically, although if you break that down to adults 18 to 30 years, it's decreased more dramatically and in a statistically significant manner.

Next slide, please.

So we look at e-cigarette use among e-cigarette users. It's clear that most e-cigarette users have ever regularly used cigarettes. In fact, the vast majority, 85 to 90% of current regular e-cigarette users, have ever regularly used cigarettes. So these analyses, cigarettes are expanded to include not just traditional cigarettes, but roll-your-own, cigarillos, and tobacco heating cigarettes; gives you an idea of some of the categories we look at, but we wanted to be all-inclusive here. So those numbers for the NTBM for current, about 86%. Little higher with ever. And the numbers are slightly above 90% when

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we allow people to self-define. So it's clear that, again, the vast majority of current regular e-cigarette users or ever regular e-cigarette users have regularly used cigarettes.

Next slide, please.

But nearly all of these people used e-cigarettes after using cigarettes. So among U.S. adults, 97% plus who have used both products sometime in their life have used e-cigarettes after using cigarettes, and the data are fairly compelling: reasonably large sample sizes, 98.4%; 97% from NTBM and 97 and 98% for TTM. In the NTBM, since we do ask about month and year started, we do have a number of people, a small percentage, which is noted in the footnote, who have indicated that they started both products at the same time. But it's a fairly small number, somewhere around 4 or 5%, if I recall.

Next slide, please.

So when we look at current e-cigarette users who used e-cigarettes after cigarettes, we find that about 25% of them are, in fact, former smokers. We define former smokers as having quit 6 months or more. And so the numbers, again, are fairly consistent in both surveys, and this is fairly -- again, I think fairly consistent with what you've seen in some of the published reports. It's not to say that people are using

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e-cigarettes to quit; it's just an acknowledgement or a recognition that among those that have used e-cigarettes after cigarettes, about a quarter of those are former smokers. The surveys allow us to look at other tobacco product use, but for these analyses, we're really focused on product order among the U.S. population, U.S. adults specifically, for e-cigarettes and cigarettes.

Next slide, please.

So, in terms of cigarette initiation among e-cigarette users, the data we have show fairly convincingly that e-cigarettes are not a gateway to cigarettes among the vast majority of ever regular e-cigarette users. This takes into account not just those people that used cigarettes before e-cigarettes, it also takes into account the people that used e-cigarettes prior to cigarettes or have used e-cigarettes and never went on to cigarettes. So you see that, for example, in the NTBM, you're talking about 120 people out of almost 5,000 that could be potential gateway smokers. Again, this doesn't take into account what they actually started tobacco with, but they clearly used e-cigarettes prior to using cigarettes. Given the short amount of time that e-cigarettes have been on the market, I think it's fair to look at whether those people

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have remained smokers. When you look at whether they're current smokers still, the numbers cut down to about 1.3 and 1.5% in the respective surveys.

Next slide, please.

And if you wouldn't mind, just go ahead in blowing out those bullets. There's four bullets. So the data from RAIS' NTBM and TTM surveys, weighted to reflect U.S. census data, indicate the prevalence of current regular e-cigarette use among adults is 5 or 6%, that the vast majority, 85 to 90% of current regular e-cigarette users have ever regularly used traditional cigarettes but nearly all of those used e-cigarettes after using cigarettes. About one-quarter of those individuals are now former smokers. The data are fairly also compelling to indicate that e-cigarettes are not a gateway to cigarettes among a vast majority of adult, U.S. adult, ever regular e-cigarette users.

Next slide, please.

So while we appreciate that there's limits to cross-sectional data, and we have gone to great lengths to look at behaviors in a retrospective manner, looking at and asking questions on what products were actually initiated with, for one survey, all the way to brand and style, I've also kicked

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off a study in Colorado. It's a postmarket surveillance study of our digital product use, and in that study, we'll be collecting representative data on use behaviors among tobacco users and nonusers. The study was initiated about 18 months following VUSE market launch, so we could actually identify e-cigarette users and VUSE users.

The study consists of four waves of a dual-frame random digit dial. We're talking to 6,500 people -- I'm sorry. We're collecting data on 6,500 people per wave, and there's also a variable e-cigarette user oversample per wave. The baseline was conducted or completed in the end of last year. We're in the second wave now of collecting data, and each of the waves will go 6 months.

Towards getting more granular data on e-cigarette users, at each of the panel waves, we will be recruiting e-cigarette users to join a panel to follow their behaviors over time. The hope would be that some of these longitudinal data will help us make stronger inferences for the cross-sectional data, and we've also come to recognize, and something that maybe should be discussed today, is that not all e-cigarettes are alike, at least that's the proposition going forward. So we've separated the vaper category into, for example, e-cigarettes that look

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like cigarettes and e-cigarettes that do not, such as tank systems. We also look at e-hookah and a number of other things.

So last slide, please.

This is our disclaimer/acknowledgement. As I mentioned, I work for RAI Services Company, which is a wholly owned subsidiary of Reynolds American, and this organization bears primary responsibility for coordinating implementation of the Tobacco Control Act or RAI's FDA-regulated tobacco operating companies. The research was conducted in conjunction with GfK Public Affairs and Corporate Communications, which is a division of GfK.

Thank you for your time and attention.

(Applause.)

DR. DRESLER: Okay, thank you.

And our next speaker is Dr. David Abrams who will be speaking on Operationalizing the Public Health Standard: What the Science Tells Us About E-cigarettes.

Dr. Abrams.

DR. ABRAMS: Thank you. It's a pleasure to be here today. These are my disclosures.

What I'll be talking about today is the big picture. How

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do we operationalize the population impact, and what are the key tipping points? First I present a framework of stocks and flows and trajectories. Second, among nonusers I will give specific examples and cautions about how to interpret the data given the state of the science. Third, I will do the same for current users of tobacco products.

And then I will summarize and hope to show how critical it is to know the key trajectories and the states, their causal directionality and their interdependence before we make decisions that have very high stakes about population harms versus benefits. I will only briefly highlight the examples because we will be submitting a full report to the FDA docket that backs up what I'm about to say.

In terms of the big picture, the Surgeon General reminds us it's combustibles that cause the primary deaths, and this must always be kept in mind. It's a complex process of inter-relationships, and like the blind men and the elephant, we must be very careful not to overly latch onto one part at the expense of other parts and perhaps make premature judgments about public health impact. And, of course, any regulatory framework should emphasize prevention of youth uptake of any and all tobacco or nicotine products.

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The framework is guided by the harm continuum with the extremely toxic combustibles on the one side that are orders of magnitude more harmful than the less harmful non-combustibles, which include snus, e-cigarettes, and alternative delivery devices, nasal sprays, oral products, and medicinal NRTs. And, of course, again, for nonusers, no harm at all means no use at all.

In terms of a public health framework, we must identify all the shifts and trajectories that can have ultimate population impact. While appearing complicated, the core elements are quite straightforward. We are about to publish a prototype Markov model that has the five key elements that embody the entire population. We start, of course, with nonusers, particularly youth, and of course, we want to keep this as sticky as possible and keep as many of the nonusers as we can. But some of them with vulnerabilities will progress either to the left, in red, to much more harmful and toxic cigarettes or combustibles -- and I'll use those words interchangeably -- or to the right to experimenting with much less harmful products. And in this case, there's great interest in e-cigarettes. Dual use is a transitional state, and it's really important in longitudinal research to

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understand the stocks and flows into and out of dual use and whether they're primarily going from the right to the left to more harmful substances, or the left to the right to harm minimization.

And, in addition, of course, we're most interested in migrating to former use, particularly of combustibles, and so we want to see the stocks and flows primarily down to the bottom. So the top half is largely about youth prevention and the middle and -- the bottom half is largely about adult cessation and reducing the death primarily due to combustibles but ideally all products.

This is a more mathematical depiction of that model and shows how simple the five categories are. All you keep in mind is at the top, no use in green; at the left, most harmful use of combustibles; at the right, less harmful products; and at the bottom, migration to former use among current users. Now, let's look at how this roadmap informs the big picture, first for nonusers, particularly youth, and then for users. So we look forward and have just seen some of the rich depth in the Monitoring the Future's data, and I'll just pick one example of why it's important to have a full picture.

We do know that 17% of 12th graders have experimented in

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the past 30 days with e-cigarettes. But looking a little closer, 76% of them are already using cigarettes and are therefore dual users. Even closer, if you look at the proportion who are dual using, we actually find that 5.6% or almost a quarter of them were past cigarette users in their lifetime but have only smoked, used an e-cigarette in the last 30 days.

So this could actually be a trajectory from left to right out of cigarette use into e-cigarette use. While we don't know from cross-sectional data and need longitudinal data, this simply makes the take-home point that we must avoid narrow and over-interpretation of one trajectory within the bigger picture at the expense of others. All the trajectories and states are needed to inform the big picture of harms and benefits and the ratio to the population.

Another example from the NYTS data where we also look forward to more in-depth analysis of the 2014 data. One of the points, I think, that needs to be emphasized is although e-cigarette use is indeed up, and that's of great concern, and that it's exceeded the 9.2% from cigarette smoking, we must bear in mind actually that it's total combustible use that causes the most harmful exposures.

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So we do not yet have the calculation for total combustible use, but it's a combination of little cigars and flavored cigarillos and hookah and cigarettes combined. We do have those data from Monitoring the Future, and it's 21% for total combustible use. That's a roadmap trajectory we must keep firmly in mind and allays the focus.

So mentholated cigarettes, flavored little cigars, and cigarillos and hookah clearly attract youth. In fact, almost 50% of them. All combustibles, therefore, must be made less appealing and attractive. And so in a bigger picture model, this must be kept firmly in mind in terms of the context of overall public health, harms versus benefits. There are other considerations as well. Past ever use and even past 30-day use is very fleeting. We really are interested in the harmful exposure of progression to regular use.

Recent studies by Kozlowski, Giovino, and now by Ken Warner reinforce this point, but none make the point better than the raw Monitoring the Future data where you can see the dramatic drop-off between lifetime cigarette use in blue, 30-day in red, and daily use and more than daily use. Lifetime cigarette use and daily use is what we need to see for the conversion to be concerned about harm. And we know almost

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nothing about the conversion from experimental 30-day e-cigarette use to even regular cigarette use, let alone the conversion to more lethal combustible use. This has to be kept in mind when making decision-makings.

We also saw a very nice presentation from the Monitoring the Future data on the gateway theory. The concern about youth e-cigarette use is often based on the gateway. However, science has pretty much replaced the gateway theory with the common liability model, as you saw presented earlier this morning. The bottom line is a cluster of behaviors travel together, and I'm not so sure that any one of them is a gateway to the others. They all are shared liability markers. So youth have qualities like curiosity, sensation seeking, and other risk-taking vulnerabilities which drive all of these substance use behaviors and have vulnerabilities that may not even be emerging until they use one of those substances. This has huge implications for how we interpret trajectories and transitions and early use episodes in an overall public health model.

A bigger problem is that we see premature drawing of causal directional inferences from correlational cross-sectional data despite the correlational nature and the cross-

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sectional nature being acknowledged. Both Pentz and Wills, I think, are rightly cautious and examine the underlying common vulnerabilities in the interpretation of cross-sectional data, and however, I would take a different view of Wills' data than Dr. Dutra just did.

Others have not been so careful in their interpretation of the directionality of causality. And seeing a correlation between use of e-cigarettes and cigarettes does not mean one caused the other. We have written extensively about this, both in terms of the caution and using scientific methods to guide us. We have to be really careful, the stakes are high, and several studies have called for caution in this regard.

So, in summary, in terms of nonusers, here are some take-homes on this slide. We must keep in mind all the stocks and flows in the various states and limit that -- the current data are limited. We need longitudinal data and flow of trajectories over time to predict net public health impact and inform a big picture roadmap.

Now, let's look briefly at users and the issue of cessation, dual use, and exclusive use; in other words, harm minimization due to e-cigarettes. Since my colleague Dr. Pearson will provide details later, I'm going to go very

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quickly through the data here just to the take-home points. But perhaps even more than the youth data, there is misinterpretation of cross-sectional data that has been the basis for many premature conclusions and a rush to judgment that e-cigarettes are negatively related to harm minimization and cessation of more lethal combustibles.

For example, the meta-analysis that was shown by Dr. Dutra, I think, includes some of the major flawed studies that I believe are uninterpretable, not just difficult to interpret, given the flaws in the data. And so the same meta-analysis, which includes almost all the studies published to date, I would say the following studies need to be deleted because they are uninterpretable and uninformative of the relationship between e-cigarettes and cessation. If you delete these studies, you see a very different picture, and although the data are still very preliminary and we need more randomized trials, there is more promise than negative data in terms of what's out there if these studies are ignored.

The bottom line is that some of the better control studies with better measures indicate about a 20% cessation rate for e-cigarettes, and the two randomized trials, although early and with very early products, also reflect somewhat that

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e-cigarettes may be at least as powerful as NRTs but have much greater reach and population impact as evidenced by the United Kingdom study where they have surpassed the use of all other medicinal NRTs in aiding cessation in the UK. And they also have roughly a 20% quit rate, albeit again an observational, not randomized trial.

So the bottom line on terms of cessation, we definitely need more rigorous studies. E-cigarettes, however, can increase quit attempts, reduce cravings, be a reduce-to-quit strategy in the transitional dual use, which is a crossroads, not necessarily a way station, and they can prevent relapse. A final thought: to maximize the benefits of both harm minimization and cessation, as has been called for, there needs to be an integrated nicotine and tobacco policy across CDER and CTP with fast-track approvals in both areas to maximize the benefits and minimize the harms and accurately educate the public about the value of safe, regulated e-cigarettes.

So the swirl and unknown current status of most of the data, and while we wait for longitudinal data and more rigorous studies where we learn how to ask the right questions to inform the right impact on the big public health model, we still feel this does not change some basic commonsense issues. And, of

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course, one of the ones we are most concerned with is preventing sales and marketing that target or appeal to youth.

So, in summary, remember the blind men and the elephants and Goldilocks. In terms of youth, there are dramatic declines in cigarette use, total combustible use is still of great concern, and the uptick in e-cigarettes, of course, is a concern as well. Use of e-cigarettes for cessation or harm reduction is quite promising if you eliminate the flawed studies, and we need longitudinal trajectory data plus a big picture model with modeling and mapping of all the pathways in order to make sure that we don't emphasize one piece of the elephant over another. And Goldilocks was right. At the end of the day, the stakes are incredibly high.

We must be rigorous and skeptical of the interpretation of data based on current sparse evidence, and I would also say that replication of "me too" flawed studies does not increase their robustness or convince anybody that the data are stronger than they are. I believe the scientific method and the truth will prevail, but we must be very cautious about rushing to premature judgment with one piece of the model while ignoring others and risking making public health harm rather than benefit.

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Thank you.

(Applause.)

DR. DRESLER: Okay. We're going to come to the panel discussion at this point, and we'll do clarifying questions at this point also. So I'd like to remind everyone if you have questions, people are in the aisles with cards, so if you'll please write your questions on the cards. Legible helps me a whole lot, please. And then pass them to the people, and they will bring the questions up, and I'll get those. And will the speakers please come up as your name tags are coming up, so if you'll come on up to the front. And we'll go with clarifying questions and questions that we'll start in for the panel, please.

(Pause.)

DR. DRESLER: So Dr. Curtin is still on the phone, so I will try and be good to remember to see what his comments are as we go forward. And then for our transcriber, let me just -- Dr. Abrams, Dr. Dutra, Dr. King, and Dr. Miech, okay? All right.

So clarifying questions. Do we have clarifying questions coming up? Those cards will be coming to me. I have one question, so Dr. Abrams, this is -- you know, Dr. Bullen's

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papers talked about a whole lot. He had in his discussion that he didn't power the study to look at cessation differences between patch and e-cigarettes. And I keep hearing people say that, you know, this is evidence for cessation, it's not different than the patch, but he even says in his paper it's not powered to say that.

(Off microphone response.)

DR. DRESLER: Yeah, the -- yes, please.

DR. ABRAMS: Yeah, that's an interesting point. The way I read the abstract in the paper is that it's appropriately conservative. I think the results that he's based on are the 12-month continuous abstinence, which were frankly quite modest and showed no difference between e-cigarettes and NRT. And I think he was perhaps implying that with more power, there would have been a difference in favor of NRT, although he didn't -- I'm sorry, in favor of e-cigarettes.

But it's more complicated than that because there were adherents and confounders in that study. For example, the nicotine was a coupon that they had to redeem and the e-cigarettes were given with easy access, so there are some real methodological internal validity problems with the study.

But I think what's missed in the study, and I have that on

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my slide, is the following: If you use the 6-month, 7-day point prevalence criterion of abstinence, not the one in the abstract, because that is the gold standard in the PHS clinical guideline and the Cochrane Initiative, you get a 21% quit rate for e-cigarettes and a 15.7% quit rate for NRT, still not statistically different because of power, but that doesn't mean that you would invalidate the fact that they are at least as good using the gold standard criteria of the PHS outcome guideline as NRTs. And they're arithmetically a little bit better.

So if you use an apples-to-apples comparison with the other 80 arms of the Cochrane reports on randomized trials of NRT versus placebo, both the NRT arm of the Bullen trial and the e-cigarette arm are well within the confidence interval of expected outcomes from NRT studies. And, therefore, I think we can say with confidence from that study, although it's an early study, it is underpowered, and it uses an inferior first generation e-cigarette product, that it's at least as good in that study. We clearly need more rigorous and many more studies.

DR. DRESLER: Okay, thank you.

So we have some questions coming in. So, for Dr. Miech:

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What is the relationship between rarely use of e-cigarettes and past 30-day use of e-cigarettes? So what is the relationship between rarely use of e-cigarettes and past 30-day?

DR. MIECH: Oh, rarely use is a new concept that has just come on the block, so we don't ask about rarely use, so I'm not able to talk to that. I can't speak to that because we just had the question did you use the e-cigarette in the past 30 days, and we don't break it down any further than that.

DR. DRESLER: Okay. This one is also for you. Do you take interest -- okay, I did ask for legibility, and as a surgeon, I know how bad we can all write, so did you take intensity of use of other substances -- I'm going to work on reading that one, okay? So let me ask another question and I'll come back to that.

Okay, so here's one. Can you discuss the impact of the diversity of e-cigarettes on the interpretation of the finding? So we all know that e-cigarettes are increasingly different. So how does that interpret for the findings, please?

DR. MIECH: Is that for the panel?

DR. DRESLER: Yes, for the panel. So you can go ahead and start since I started off with you.

DR. MIECH: Yeah, the diversity of e-cigarettes is an

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issue that definitely warrants more attention, at least in Monitoring the Future, than it's currently received. We just asked about e-cigarettes for the first time in 2014. It's what we call a trip wire question. We wanted to see, well, what kind of prevalence are we going to find out there, does it warrant more attention in our survey, and when we found the prevalence levels that we did, we decided we really need to ask more questions about this. So we're going to ask or we are asking now -- in fact, we have asked; the data is coming back to us now. We asked what people are smoking in their cigarettes, so whether it's nicotine or non-nicotine or whether they know or not.

But we haven't yet branched into, at least in Monitoring the Future, the different brands or types of e-cigarette devices. We asked that for regular cigarettes, and it's something that we definitely need to consider moving forward. I don't know what the other surveys have done.

DR. KING: So I think that the diversification of the landscape is really critical in terms of both the nomenclature of these products, you know, how people are referring to, but also the makeup of the products. So we're currently shifting a lot of our surveillance systems to account for, you know, what

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is the type of ENDS that's used, is it disposables or rechargeable, but I think nomenclature is also really key because people are not calling them -- obviously they're not calling them electronic nicotine delivery systems.

But they're not calling them e-cigarettes, particularly among youth, and there was a *New York Times* piece last year which really underscored that quite nicely, that they're calling them vape pens, they're calling them e-hookahs. And so really we might actually be underestimating the prevalence of use by just asking about e-cigarettes, and so our surveillance systems really need to become nimble to really catch the diversity of the tobacco product landscape with regard to e-cigarettes. We're doing that in a lot of different ways.

Among youth, we've modified the preambles to these surveys to include the diversity of products and among adults as well. And I can tell you, from some of the data that are coming out, it does indeed impact the prevalence of use. So moving forward, identifying both the nomenclature that people are calling these products but also the different types of products that people are using is really going to be critical to successfully capture the shifts in the landscape over time.

DR. DUTRA: I absolutely agree with both Dr. Miech and

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Dr. King, and I think that's one of the issues that we have with the National Youth Tobacco Survey, which I'm glad to hear is changing, is that the questions about e-cigarette use were very limited, and it's important to incorporate all these different names of the devices. I also think it's going to be really challenging in the future because it's a constantly evolving landscape, and the terms for these devices is going to continue to change.

So something that we definitely need to keep in mind, and it's going to make things a lot trickier in terms of comparing our previous estimates when we used more narrow questions to the broader questions that we are going to have in the more recent survey data.

DR. ABRAMS: And just to add to that, clearly these impact dramatically on the stocks and flows into or out of lethal combustible use and/or keeping it away from all kids. So I share some of the really strong concerns that Dr. Dutra and others raised, that the new products, because perhaps they deliver nicotine more efficiently, are more likely to be watched with respect to kids' experimentation, and that would be a real concern. It's a double-edged sword, and you still have to thread this needle between the advantage of finding a

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way to keep all of this out of the hands of kids as we do now with combustibles and redoubling those efforts for all tobacco and nicotine products without overly demonizing them for adults who might be using them to quit or reduce their harm. So it's a bit of a double-edged sword. The more appealing, satisfying, and perhaps somewhat more addictive the new generation products are, the more we worry about them for kids experimenting, getting hooked, and progressing. However, the big public health advantage is the more they actually help and have better outcomes for adults, we just don't know.

We need to track this very carefully in longitudinal studies, and I do believe the PATH study has some of these questions in it, and the public access to the Wave 1 and Wave 2 PATH, I think people should look at so that we can harmonize and standardize questions across surveys to have a better handle on the dose, the type of product, and how and why they're being used both by adolescents and adults to maximize benefits, but for sure, keep them out of the hands of kids.

DR. DRESLER: Okay, that sort of morphed into the next question, but let me get to Dr. Curtin on the phone.

Dr. Curtin.

DR. CURTIN: Yeah. I appreciate it, thank you. If I

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could comment on the last question. I agree, it's important to differentiate these products because it's an evolving area. We started doing that in some of our surveys, the NTBM and the TTM. I think we started probably back in February, so we've only got 3 or 4 months of data to look at, I think 3 months of data to look at.

And we find that when we were capturing just e-cigarette use and now we can define it, if you will, e-cigarettes that look like cigarettes and those that don't that are tank system and such, it would appear that most e-cigarette users, regardless of how they -- what kind of product, that they still consider themselves e-cigarette users, so we haven't seen a bump in prevalence when we added the tank questions. And so that's encouraging that we have been capturing these behaviors. We'll continue to monitor that. It would appear that about a third of the people that we talked to are tank users and the other two-thirds are e-cigarette users that look like cigarettes.

In terms of the Colorado study I mentioned, we saw early on, and part of it was predicated on the baseline data there, that we needed to do a better job in using the vernacular of these product users. And our intent there is, again, to follow

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these people more granularly in the cohort study. At least the current thinking is that given that everybody's history and trajectory is going to be different, that we would attempt to bucket these people much like the stages and trajectory buckets that have been suggested by Carabello and others and then to track their behaviors, their dependence measures, their cigarette consumption measures, whether they quit or not over time based on those different stages and trajectories.

We don't know what it will look like for e-cigarette users, if it's going to be the same as traditional cigarettes, but I think it may play to our advantage that a number of people that we are -- adults that we're talking to in Colorado are fairly early adopters, so maybe we can get a good sense of some of the issues that have been brought up, particularly by Dr. Abrams, on what dual use looks like, is it a transition to another place. But these are all things we hope to report on.

DR. DRESLER: Okay. So let's follow up with a little bit of his response and then what Dr. Abrams had brought up. So if we're looking at what type of studies can evaluate the impact of e-cigarettes on youth tobacco initiation, okay, so what studies, what methods can be used to determine the portion of youth and young adults who would not otherwise have initiated a

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tobacco product? So what are the methods to get at the key questions? So we've heard data, but are there any other methods or ways we can look at?

DR. MIECH: That's the million dollar question, the 10 million dollar question. With youth, we can't do a randomized controlled trial, of course. We can't assign some youths to start smoking e-cigarettes and see what happens to them, see if they become cigarette users or not. So what we have to do is something observational.

It's been noted many times by the panel members that we need a longitudinal study where we follow people. My study shows 8th and 10th grade would be particularly strategic in which you would zero in on those 8th and 10th graders. You have a lot of e-cigarette users who are not yet using cigarettes or any other drugs. And then you would give them quite an extensive battery of questions about their attitudes and attitudes about drug use and other factors that have been mentioned here, such as risk taking behavior and stuff like that, and then follow them over time and see what happens. And I think that's the best design we can do scientifically, the most valid one we can do to answer that question about whether people are using e-cigarettes, are doing that instead of using

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cigarettes, and if they're progressing to other types of drug use.

DR. DRESLER: Longitudinal study, is that what you said? Okay.

Dr. King.

DR. KING: So, you know, obviously I agree, you know, we need prospective studies for going forward. There's obviously limitations related to randomized clinical trials. Obviously, we can't conduct them from an ethical standpoint, but I don't know many parents that would offer their children to participate in those studies.

But in the interim, I think that it's important to be, you know, cautious and use what we currently have and that a lot can really be gleaned by the cross-sectional data that we do have. So although we obviously want longitudinal studies and those will provide a breadth of information, there's still quite a bit that we can glean from the cross-sectional data, particularly among the youth and the exponential increases that we're seeing over a short period of time. So certainly longitudinal is critical, but there's still a lot of information that we can learn from cross-sectional, do our public health diligence to address the issue.

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DR. DUTRA: I absolutely concur. I think there -- you know, certainly we have to be very careful how we're interpreting the cross-sectional data which has a lot of limitations. And we certainly need longitudinal studies, absolutely. But in the meantime, my concern is what's going to happen while we're waiting around for that to happen, and we do have quite a substantial body of evidence now.

It's particularly important to try to figure out, you know, are kids -- why are kids using these devices? Are there kids who are smokers who are trying to use e-cigarettes to quit? And to keep in mind, too, that NRT is not recommended for kids, and so we're looking at a different landscape of nicotine use, and any nicotine use among kids is a problem.

DR. DRESLER: Let's follow up on that, too.

DR. ABRAMS: Can I add my two cents?

(Laughter.)

DR. ABRAMS: Just two cents.

I concur with most of what's been said here. However, I do think, as I said, that cross-sectional studies do not imply a causation, and so it's one thing to say this is cross-sectional, we cannot infer causation. But then if you then go on to infer causation and emphasize only the direction of

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e-cigarettes triggering more dangerous cigarette use, you have just violated that assumption. So, unfortunately, the cross-sectional data has to be extremely cautiously interpreted, and you'll hear more about that from Dr. Pearson and some other studies we've done.

Secondly, I would recommend that we all look again at the excellent longitudinal science of Dr. Laurie Chassin, who has done a long-term trajectory and patterns of use analysis from, I think, roughly age 14 to age 30. Now, we cannot obviously wait that long for data, but I would argue that unless you use harder measures of outcome like progression to daily or regular cigarette use or combusted use, as well as some decent amount of time, at least 3 to 5 years, to allow some kids who were experimenters in adolescence because of all sorts of reasons, as we all agree, but who will largely grow out of it. And Laurie Chassin's data is even more sobering than the Ken Warner and Kozlowski studies that I mentioned about, that past 30-day use is not a measure of current use and is too soft a sign of a warning of what's going on. Her data suggests that even kids age 15 to 17 who progress to weekly and daily use, about a quarter of them grow out of it by age 20 to 25. So we've got to be --

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DR. DRESLER: So wait a second.

DR. ABRAMS: -- very careful. Yes.

DR. DRESLER: Yeah, let's go back to the point of the question, though.

DR. ABRAMS: Yeah.

DR. DRESLER: Okay. So what methods, not what are the results, but what methods?

DR. ABRAMS: No, but this is a method because it says you need longitudinal data, you know, representative sample of youth, and you need to follow them for at least 3 to 5 years, and be very cautious of over-interpreting experimentation that may or may not be a canary in the mine marker of anything other than experimentation.

DR. DRESLER: Okay.

Dr. Curtin.

DR. CURTIN: This is Geoff Curtin.

I'd like to add just a couple words as well. I agree with a lot of what Dr. Abrams just said, and we've geared our tools that way, but a given that we are going to have to rely on cross-sectional data, at least for the short term. And it seems to me that augmenting some of these youth cross-sectional surveys to include metrics on who is at risk for tobacco use,

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as has been discussed by others, maybe putting in questions on product order and towards what Dr. Abrams just said at the last of his talk, allowing us to define users of these products.

You know, cigarettes, combustibles, e-cigarettes, other products based on more than just if you ever used it in your lifetime and was it in the past month isn't really a great metric. I mean, there can be questions added to actually define who's actually using these products, regular users, some are all days, to actually, you know, track what's going on in the population.

DR. DRESLER: Okay, thank you.

So I have a whole bunch of questions. So let's go for as succinct as we can go, all right? Is there any evidence that adolescents use e-cigarettes to quit tobacco? Any evidence in the 18 to 24 or the 18 to 30 that they use e-cigarettes to quit?

Dr. Abrams.

DR. ABRAMS: I would say yes, but it's sparse, and I would not over-interpret any more than I would want to over-interpret things the other way. But there is uncontrolled and not very good studies suggesting that some kids are using it to quit smoking.

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DR. DRESLER: What age groups are you talking about?

DR. ABRAMS: I've seen some of the data from the UK that suggests that it's in the 15 to 21 group, but more strongly in the 18 to 25 group. And, again, I wouldn't over-interpret the data, but the Monitoring the Future data that I described, if you pause the current e-cigarette users, there are 5.6% of them that used cigarettes in the past but did not use e-cigarettes in -- did not use cigarettes in the past 30 days but were using e-cigarettes in the past 30 days. Because we didn't ask questions about how and why and we don't have even better questions --

DR. DRESLER: So limited data.

DR. ABRAMS: Yeah. But those data suggest that those 5.6 may well have switched from cigarettes in the past to e-cigarettes now.

DR. DRESLER: Okay, all right.

Dr. Curtin.

DR. CURTIN: Yes. I mean, we have the ability to go back and stratify by younger adults. The only data I have that we presented and I have access to right now is -- and, again, it's not suggesting that they actually used e-cigarettes to quit, but among that large percentage of adult smokers that have used

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both products, so they're current e-cigarette users now and they've ever regularly used cigarettes, about a quarter of those no longer use cigarettes, and these are people that are still using e-cigarettes. So it does somewhat match some of the data that Dr. Abrams was just referencing.

We are asking questions in the Colorado study on intention, because we think it's important going forward, but we just finished the collection of all the data in the baseline, and we're doing the first panel wave now, but we hope to be able to inform that. I know that doesn't speak to the youth question, but we will be able to at least stratify those people, provided we have a sample size that warrants it on the young adults ages 18 to 24. In our rolling cross-sectional studies we can do that now, and it's something that we are working on.

DR. DRESLER: Okay.

Dr. King.

DR. KING: Yeah. So the way the question was originally framed was youth, and so, I mean, the answer to that is no, we do not have the data. There are currently, you know, studies underway that are attempting to look at this, and you can extrapolate from data among young adults, but the caveat there

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is that the sample is very small, and it's limited, and in some respects, you don't even have the statistical stability to even look at it in a meaningful way, so I wouldn't over-interpret some of this data among young adults. But in terms of youth, I'm not aware of any current surveys that have inquired about the use of cessation for e-cigarettes from conventionals.

DR. DRESLER: Okay.

DR. DUTRA: I absolutely agree. And I think Dr. Abrams and others have really pointed out the problem with, you know, without directionality, we don't have causality, and there aren't longitudinal studies that have looked at smoking cessation among kids who are using e-cigarettes or not using e-cigarettes in the past. But in the current environment, we really don't have that data, and that's something that we absolutely need to see exactly what's happening. We also need very specific questions about actual smoking cessation, so both quit attempts and successful quitting, measuring all of those different aspects of quitting behavior, to be careful what we say about all those different -- the different data that we have based on the wording of the questions.

DR. DRESLER: Okay, does survey data show higher teen or adolescent e-cigarette use if the parents use e-cigarettes?

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DR. DUTRA: I know there's certainly data on -- there's data on how open kids are to e-cigarettes, and there's data on -- there's data actually on the kids whose parents who smoke are actually more likely to use e-cigarettes. The name of the study is escaping me right now. But as far as I know, I don't know if there's any data actually on parent use of e-cigarettes and kid use of e-cigarettes. I know people are trying to work on that right now.

DR. DRESLER: Dr. King and then Dr. Abrams.

DR. KING: The short answer, we don't know now. We added a question to the National Youth Tobacco Survey, and we get at if someone who lives in the home uses e-cigarettes specifically, so in the future we will have the data, but currently at least, at the federal surveillance level, we do not have it.

DR. DRESLER: Dr. Abrams.

DR. ABRAMS: We don't know, but I would also say that there's very strong data that when parents smoke, it's the strongest predictor of whether adolescents will both smoke and progress to daily smoking. And that includes ruling out or at least controlling for in utero exposure. So we have very strong data that adults influence their kids for cigarettes. I

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would expect the same for e-cigarettes.

I wouldn't be surprised if there were strong correlations there. They do reflect, I think, frankly, none of the data and whether we know or do not know, and we don't really know the answer to some of these very important question changes, the policy that we ought to aggressively double down on keeping all tobacco and nicotine away from kids at a very high level, whether it's new products or existing products, whether it's flavored little cigars.

DR. DRESLER: Good, that's good.

DR. ABRAMS: So --

DR. DRESLER: The question was just about e-cigarettes and parents.

DR. ABRAMS: Yeah.

DR. DRESLER: Okay. So --

DR. ABRAMS: But we need --

DR. DRESLER: -- I got a whole bunch of questions --

DR. ABRAMS: No, but --

DR. DRESLER: -- to go through.

DR. ABRAMS: Okay. But the point is keep the balance. We can't lose one piece for the others when we're talking about public health impact.

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DR. DRESLER: Absolutely.

Okay, so the question is about what are the differences and patterns of use by race and ethnicity? So comment and discussion about --

DR. KING: So I presented some data on adults earlier today. It slightly varies from conventionals, but you do see higher prevalence of use. The highest is among the non-Hispanic other population, so that can include a mix of multi-racial as well as other groups. But currently that's the highest prevalence use from the National Adult Tobacco Survey. You do see slight variations between non-Hispanic whites and non-Hispanic blacks, but otherwise, in terms of adults, that's the bulk of the variation. There's still high prevalence of use among most populations. Among youth, it's fairly comparable, but there are some racial/ethnic differences, but I don't know if other people on the panel want to speak to that because that was the focus of the presentation. But among adults, the highest prevalence of use is non-Hispanic other adults.

DR. DRESLER: Dr. Miech.

DR. MIECH: In Monitoring the Future, which focuses on adolescents, we found that prevalence was pretty comparable

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among the different racial/ethnic groups, but lowest -- the exception is that it was lowest among African Americans or blacks, which is what we found in the past for use in most drugs at this age among adolescents, that African Americans have the lowest levels of prevalence.

DR. DRESLER: Why?

DR. MIECH: Well --

(Laughter.)

DR. MIECH: I don't know. I said it. I don't know. I don't know why African Americans have the lowest levels. There's actually whole literature on that that posits different types of potential reasons for that, that maybe they are more likely to have what's called unfortunate examples of people who have used drugs, it could be that they live in neighborhoods that are more likely to give them greater exposure to the negative effects of drugs, but I think the answer's still out on that.

DR. DRESLER: Anyone else?

Dr. Curtin.

DR. CURTIN: Yes, this is Geoff Curtin. And I know our surveys looked at adults, but we see some of the same things. The highest prevalence, some early analyses we did were among

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non-Hispanic whites, but there was a surprising, I think, somewhere in the 20's, 30% among Hispanics, where non-Hispanic blacks, the numbers were probably in the teens, and that caught our eye and that was a minority group that was a little higher. In terms of age, we see that, at least among adults, the greatest prevalence is really among your middle-age adults, but we've seen some of the same thing with the racial breakdowns.

DR. DRESLER: Okay. And, Dr. Curtin, this one is for you, also. Do you do analyses of 18- to 24-year-olds regarding starting with e-cigarettes before cigarettes? Is that part of your surveys? So, you know --

DR. CURTIN: Yes, we can look at that. We haven't looked at it for this particular dataset. We know that -- and I think I was in and out on some of the earlier presentations as we were getting set up to do this by phone, but it seems to me there was some data presented by someone suggesting that about somewhere around 10% of current e-cigarette users have never used cigarettes.

Our data shows about the same thing. Now, we can go back and look to see if they actually started with e-cigarettes, but as I mentioned during the talk, we were only focused on the product order for these two particular categories. I think we

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did go back and look real briefly at about 90% of that 10% were actually starting with e-cigarettes, but at least among adults, we don't see a gateway effect among adults. So of that 10% that start with e-cigarettes, very few of them go on to be cigarette smokers and very few of those go on to be continually smoking cigarettes, but we can go through and look at that age demographic and find out what they initiated with and where they go from there.

DR. DRESLER: Okay. So this was going back to the first, one of the first questions. Dr. Miech, did you take intensity of use of other substances into consideration for e-cigarettes, not just poly-use? But how much did they use as related to e-cigarette use?

DR. MIECH: No.

(Laughter.)

DR. DRESLER: All right, thank you.

All right, so given the dramatic but recent spike in ENDS or e-cigarette use among adolescents, are there projections in how the usage population, poly-use, e-cigarette only, or no substance use will shift over time? Specifically, will the usage patterns of today's 8th graders mimic today's 12th graders and adults as they get older? So I think what it's

asking is you were 50/50 and went up to 80. So how do you think that's going to project into the future?

DR. MIECH: Well, it's such a changing landscape out there right now, especially when the FDA announced its deeming rules, which should happen soon, I suppose, that may have a big effect on the prevalence of e-cigarettes. I don't know what's going to happen there. So I'm not going to be so bold as to make any predictions about the future.

DR. DRESLER: Okay. Anybody else?

(No response.)

DR. DRESLER: Okay. So the harm continuum always seems to show electronic nicotine delivery devices as being slightly more harmful than NRTs. What data is this based on?

DR. ABRAMS: Well, again, it's a moving landscape with new products, and there are some difficulties here because the products vary, and clearly, some of them, if abused or not used as indicated, can cause more harm or release more chemicals, as in the formaldehyde study that got so much press.

The good news from the formaldehyde study, however, was that when used as expected and indicating there was zero formaldehyde in common everyday use of those e-cigarettes, so it's hard to make generalizations because the quality and the

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types of products out there are so variable.

But by and large, I think Steve Hecht's study from Minnesota that followed e-cigarette users for over 6 months and looked at all the hard biomarkers of cancer showed pretty much non-detectable or certainly non-dangerous levels of all the carcinogens. And while clearly e-cigarettes are not harmless, they have nicotine, which is a teratogen for pregnant moms and not good for adolescent brains, they are dramatically, not on the orders of magnitude, but off the cliff less harmful. The estimates from other studies, including Goniewicz's work and others are that they're between 10 and 400 times less harmful on many, many markers, including metals and other substances than they -- when compared to combustibles that are basically off the charts.

DR. DUTRA: I think the most important thing to communicate to the public is that less harmful doesn't mean harmless, and that these products contain a lot of chemicals that are harmful in notable levels. And, you know, we can make all the comparisons that we want, but the fact of the matter is that it's a problem that they're not regulated and that these devices, you know, we don't know what the established levels are across different products, and that bottom line, they're

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not harmless and they shouldn't be used indoors.

DR. DRESLER: Okay. All right, here's a question that's -- okay: Surveillance of e-cigarette use and trends is challenging. How do we balance the need for consistency in questions that are necessary to establish trends with the need to stay current with the changing marketplace? How do you do that?

DR. KING: I can attempt to answer that one. So I think that you really have to have a lot of different surveillance systems, so, you know, we need these robust -- several tens of thousands of respondents to assess a lot of these indicators, but we also have a lot of emerging modes of assessment that we have accessible to us, most notably web panel surveys. And you could probably debate for a whole day about the validity of those, but for the most part, a lot of the findings are fairly consistent with random digit dial when we're looking at e-cigarettes and other indicators.

So I think, in order to look at the issue, of course we have to be -- adhere to the science and the validity and reliability of the measures, but we also can be nimble with a lot of these new surveillance tools to actually get at some of these more nuanced questions that we have and maybe even some

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split sample surveys where we're looking at, you know, what is the impact of using an every day, some day, rarely versus the past 30-day, and what are the variations and prevalence based on how you're asking questions.

DR. MIECH: That's a very good question, and there are standard ways to ask about drugs, like have you used in the past 30 days, have you used in the past year, which are used across a wide range of surveys, and in fact, when we reported in December of 2014 our e-cigarette prevalence levels, we were surprised that they were so high. And we were very nervous that maybe we had not asked correctly or done something incorrect, and we were very relieved to see when CDC came out with similarly high numbers for the same year of 2014.

So I think there are certain standard questions that are worth asking like, have you used in the past 30 days, so that we can have standardized questions across the different surveys. And then it's always possible to go into more detail, such as have you rarely or what are the e-cigarettes that you have used, do they look like an e-cigarette or something like that, that we can break down and get more detailed questions after we've asked the standardized ones.

DR. ABRAMS: I would just add to that --

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DR. CURTIN: This is Geoff Curtin. Again, you know, we were talking about use, but some of the things that we're doing could be applied from the adult surveys into the youth surveys, and we do these online panel surveys, but they do give us remarkable flexibility, you know; we're always keeping an eye on the trend to make sure that we're not adding questions that cause complications later on. But these type of tools do allow the flexibility to, you know, add additional definitions for a product's use to address some of the issues that, in a forum like this, are raised.

So, you know, my suggestion would be that there may be other surveys that could be developed by public health like we've done in the industry that would give more flexibility and also would allow, in some ways, a quicker reporting out than having to wait, you know, a year to see what the data from last year were, so it's just a suggestion. I think if you look at the PATH and some of the other studies, you know, they've already spent a lot of time trying to come up with the best questions. We routinely refer to PATH when we're looking to add questions or modify questions and, you know, test these questions before we introduce them.

DR. DRESLER: Dr. Abrams.

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DR. ABRAMS: Just to add briefly, I would also consider, in rapid and more precise surveys, selective subsamples where you have a broad sampling of the representative sample, and then you pick informed groups that you're most interested in, in part because of the small numbers. But I think you can get a lot of mileage about then applying a drill-down strategy, for example, using ecologic momentary assessment, daily diaries. There are a variety of new informatics technologies to track, in real time, the reasons why/how, the latency, the density of use, and I think there's a wealth of data there by focusing on the micro-behavior in the actual proximal environment.

A quick example is Dr. Tom Kirchner's work with us where he's linking advertising in the proximal neighborhood of high and low income to both e-cigarette and menthol use and price differences but can actually then track individuals as they walk through that environment and finding that urges to smoke are increased when there's advertising on the outside of a store.

And so, again, this technology is incredibly available and easily used for looking at the micro-analysis of actual behavior in the environment at point of sale and among various categories of uses that would be sampled from large

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representative samples so you can appropriately scale and weight the results to perhaps more rapidly answer the modeling questions about how does that impact, and should we act sooner rather than later, because we can't wait for 20 years for longitudinal data, clearly, and especially with kids. We've got to keep all of this away from kids. So I think there's a lot there that we can do that we're not doing with new digital technologies.

DR. DRESLER: Good, because I think this is what you had, the panelists have said, and will follow in this question, and let me know if you think it's too overlapping: Discuss limitations of defining current use, past 30 days, versus frequency or more frequent use. So the last question was how are you asking the questions so that you can have the trends, but are we asking the right questions now with less than -- or past 30 days?

DR. DUTRA: I think we certainly need to drill down more and get an idea of the specific patterns of use, not just asking about have you used in the past 30 days. But one of the things that's really tricky about e-cigarettes is figuring out, you know, what kind of device are they using, are they puffing on it continuously, so I think it's just made things really

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tricky in terms of those measurements, and I think, you know, we should definitely apply a variety of methodologies like Dr. Abrams pointed out, using EMA and maybe a combination of qualitative and quantitative methods to really assess out how these kids are using these devices and how adults are using them as well.

DR. DRESLER: Okay. Dr. Curtin, do you have any --

DR. CURTIN: I agree. I mean, you know, we've struggled with this as well, because for smokers it's fairly easy to figure out the number of cigarettes they smoke per day, but for e-cigarettes it's probably a combination of the number of times they've used, taking into account the number of puffs from the e-cigarette they use per time. So I think there is still a lot to be learned there to figure out, you know, what the e-cigarette profile, user profile is.

And towards something that was said before, I think it's also important to kind of understand where that fits into their total tobacco consumption. You know, are e-cigarette users primarily poly-users of multiple products, which our data seem to indicate, not just cigarettes but a lot of different products, and how they're devoting, you know, what representation of e-cigarettes is to that total tobacco

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consumption. And I think that's going to be critical as we go forward and track what their journey is towards what was mentioned earlier about this transition phase, you know, what does that transition phase look like? Are e-cigarettes 10% of their total consumption?

And we need to track that to find out if that total consumption changes and they're putting down cigarettes more and what kind of behaviors that leads to, like hopefully, you know, quitting cigarettes. But yeah, I think those are all challenges we face, and it would be good if there was more discussion on how we harmonize those things so we're all typing on the same page.

DR. DRESLER: It's interesting how that comment brings into the next question, which actually is directed at Dr. Miech, but since this is our last question, for anyone: So has Monitoring the Future ever reported trends in aggregate of youth risky behaviors over time, and has that changed? The net risky behaviors. And in other words, has the total proportion of adolescents using any substances changed over time?

DR. MIECH: That's --

DR. DRESLER: I think they're getting at are e-cigarettes making it worse, is that a whole new category or does --

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DR. MIECH: What we find, you know, Monitoring the Future has monitored these trends in drug use for the past 40 years, and we do have an overall question of any illegal drug use, and that includes marijuana. Now, it's -- well, e-cigarettes aren't necessarily illegal. But what we find is that doesn't change all that much actually, that the percentage of youth using any e-cigarettes, and I'm just thinking about, I'm sorry, using any drug, and I'm just thinking about 12th graders right now. You might find it's about 30%; it goes up and down somewhat. But the particular drugs that they're using changes dramatically over time so that in some areas marijuana is very popular, and as that receded, prescription drug abuse might go up very high. So there is less variation, I can state definitively, in youth using any drug than there is in particular drugs that are popular at the time.

DR. DRESLER: Dr. Abrams.

DR. ABRAMS: I just think that reinforces how we need to know more, even though we've got 40 years of data, some of the key things we still don't know. And to me, it reinforces the common liability model that these things travel together. About 30 to 40% of kids will experiment, and we don't know who will grow out of it and who won't very well, even from better

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predictors than the past 30 days. So I would still argue we need measures beyond past 30-day use if we really want to understand progression, particularly to lifetime exposure of the harms of use of combustibles.

DR. DRESLER: Yes.

DR. MIECH: I definitely see a lot of evidence for the common liability model, as you refer to it, but I don't want to give up on the pathway model yet, the whole pathway concept. There's a really good study by Lynskey in *JAMA* where it had a really neat research design where he had identical twins, one twin that used marijuana and the other twin that had not. And so this design controlled for all genetic influences on drug use. And what he found is that the twin who had used marijuana was much more likely later on, a couple years later, to continue using marijuana than the twin that had not. So it definitely seems that there -- I wouldn't say the pathway model is all-encompassing and that it's the only way to look at it, but I think there is some evidence that in some situations it is predictive, and that the whole idea if you use e-cigarettes or drugs, you become known as a drug user. You get invited to parties where people use drugs, those kinds of things.

And with better longitudinal data, we could really see if

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there is a pathway effect going on here or not, and I don't know. I think the longitudinal data will be interesting no matter how it turns out, so it's one of those great research questions that you'll get published no matter what you find. So I'm real excited about that. But I would like to make a case that it is possible that there could be a gateway effect here. I'll leave it at that.

DR. DRESLER: Dr. Dutra.

DR. DUTRA: I'd like to mention, too, as I mentioned in my presentation, that the kids who use e-cigarettes in the NYTS were also more likely to be established smokers, to have smoked more, as opposed to just having -- remaining in this category where they smoked less than 100 cigarettes, and that's a pretty -- that's a common measure of established smoking, or depending on the terminology when they use, and obviously keeping in mind it's a cross-sectional study.

We're not talking about e-cigarette use leading to cigarette use or vice versa. I'm just talking about the kids who use e-cigarettes were more likely to already be established smokers and to be current smokers, and that's something important to keep in mind moving forward when we're talking about longitudinal data and how we need it but also, you know,

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looking at what we already have.

DR. DRESLER: Okay.

Dr. Curtin, any final comment?

DR. CURTIN: Yeah. I think it plays off the last comment and I think one thing that Dr. Abrams pointed out. What's been missing from the literature a little is appreciation that until we understand a little more about directionality, we really shouldn't be venturing into the area of causality. I fully appreciate, at least with our adult data, that the vast majority of current e-cigarette users have in their life used cigarettes. But I think when you start looking at directionality, you see that these people were already smokers when they started picking up the e-cigarettes.

DR. DRESLER: Okay. And that -- and we have -- yes, we have finished on time. So we are going to go for a break now; it's a 15-minute break. At 10:30 we'll start back on time.

Thank you very much to the speakers and the presenters and Dr. Curtin for hanging in there.

(Applause.)

DR. DRESLER: Thank you.

DR. CURTIN: Thank you very much.

(Off the record at 10:18 a.m.)

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(On the record at 10:34 a.m.)

DR. DRESLER: Okay. After a stellar start for the first session, we are now going to move into our second session. And our second session is on Reasons for Use, Flavor, and Product Appeal.

Our first speaker is Dr. Jessica Pepper from the Lineberger Comprehensive Cancer Center at the University of North Carolina: Adults' E-cigarette Use: Reasons for Trying, Using, and Stopping.

Dr. Pepper.

DR. PEPPER: Thank you for inviting me to join you today. As she mentioned, I'm tasked with talking to you about the reasons that people first try e-cigarettes, continue to use them, and then stop using them.

I'd like to acknowledge my funders. I have no conflicts of interest to disclose.

So I'm going to organize this into three sections. First, I'm going to give you a little bit of a review of the literature, what we know so far; then I'm going to go a little more in depth about a study I did that had e-cigarette users in 2013; and, finally, I'm going to give you a little bit, sort of, take-home message about limitations of current research and

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some implications for the future.

So we've heard great talks today about the number of people using and trends and people using, but a really important part of this is also understanding why people use. And it's important for a few reasons. The main one is that it can shed light on behavior. So we know from both theory and from research that there are connections between reasons for doing something or motivations and then what your behavior is. And so understanding this for e-cigarette use, will have some implications for peoples' behavior.

So let's talk about what we know so far. So, for this review, I started with a systematic review that I published in *Tobacco Control* with Noel Brewer last year and then, of course, updated it because things change so quickly in the e-cigarette field.

So across the realm of surveys that we have, looking at why people first try e-cigarettes, there's a lot of variation in the data, but we sort of see the same set of seven reasons come out over and over. So curiosity, to quit or reduce smoking, they're less harmful than cigarettes, they cost less, to use in smoke-free places, and the recommendation of friends and family. Now, as I said, it's really hard to sum across the

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literature, and there are a couple of reasons for that. Partly, it's that these studies happen in different years and that they happen with different populations, so smokers and nonsmokers, U.S. and non-U.S. And the reasons that people used in 2010 when it was pretty much just cigalikes and they weren't hugely available might be quite different from the reasons that they use in 2014 or 2015 when we now have this really big range of products that are really easily available and there's a lot of advertising out there. So reasons are going to change. That said, summing across the literature, these are sort of the main reasons you see. They're not ranked here in order of frequency because of how different it is to sum across these studies.

So you'll notice that five of these seven reasons are really directly related to cigarettes, and it's not surprising, as we've been talking about a lot today, among people who use e-cigarettes, the very, very high rates of current smoking. And so, of course, this is sort of a reference, and it informs why people choose to try in the first place.

So now looking at some patterns across studies. For studies that include asking about curiosity as a possible reason for trying, when people include that, it almost always

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risers to being one of the top couple of reasons that people try, but it's not included in quite a number of surveys.

If you isolate current e-cigarette users, so not just everyone who's ever used an e-cigarette but the people that have used them in the past 30 days, just typically how we've been defining current use, you really see these as the two main reasons, quitting smoking and reducing smoking. So those seem to be primary drivers of first trial among people who have used in the past 30 days.

One of, obviously, our sort of public health concerns is whether people are using e-cigarettes to get around smoking bans. When that's included in surveys when people are asked to endorse whether that matters to them, it bounces around a lot by survey, but it does typically stay out of the top three reasons. So people don't tend to endorse it as a reason as much as they do some of these other reasons. You could argue that there's a social desirability bias there, that people don't want to be rude, they don't want to admit that they're trying to skirt these regulations. But be that as it may, it doesn't tend to be endorsed as a particularly popular reason.

So what's missing? You know, the data I was just sort of summarizing are really self-report surveys, and there's a lot

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you can't capture with self-report surveys. So one of the things we're missing is the influence of advertising, and we're going to hear some talks about that later today. Sometimes advertising sort of builds on these reasons that I was just talking about -- quitting, reducing smoking, health -- but it's also got a lot of other themes that might be driving interest and appeal. So portraying e-cigarettes as sexy or glamorous or appealing to youth by sort of talking about rebellion, so those things could be driving trial, as well; a little harder to capture with the kinds of surveys I'm talking about.

Social norms. As use increases, it becomes a more normative behavior; you see more people doing it. Advertising can also influence norms.

We're seeing a lot of the same promotional techniques that we've seen from the tobacco industry for a long time. Price promotions, coupons, free samples, and a lot of sponsorship of events.

Flavors is another thing that could be driving first trial, although we're going to hear some talks on that later, so I'm not going to get into it.

So those were the sort of main reasons that people try. Looking across the data, seems to be the main reasons that they

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use on an ongoing basis to the extent that we know that, based on, you know, past few days or some day, every day use, so basically it's largely the same set of reasons with the exception of curiosity and recommendation. Those seem to drive first trial more than they drive ongoing use.

If you limit it to just current and former smokers, you really see these three reasons emerging as the top three over and over again, although in slightly different orders: quitting smoking, reducing smoking, and that e-cigarettes are less harmful than cigarettes. So those seem to be really important factors to current and former smokers. Again, not very surprising because there are such high rates of current smoking among current e-cigarette users. So it makes sense that this is sort of a reference point for them.

There's less literature on the reasons that people stop using e-cigarettes, but we do see a couple of things emerge. People don't like the taste or feel, or sometimes they report that it doesn't feel like smoking. People will say that it didn't help them quit or it didn't reduce their cravings, and so they gave up on it. Poor quality or that the product breaks easily. I think we tended to see this more with some of the early model cigalikes. And, finally, that people are

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disappointed that there isn't a cost savings. So I don't know that that's important for everyone, but these are some of the reasons that people report. And, again, these aren't ranked.

So, to dig a little deeper, I'm going to talk about a survey I did a couple of years ago, and I'm also going to return to this idea of whether or not there's a connection between motivations and behavior. So the PI for the study who ran the study was Sherry Emery at the University of Illinois at Chicago, and I collaborated with her and some other researchers at UNC. It was a web survey in 2013, a combination of a representative web panel and a convenience sample that were combined and weighted. There were over 17,000 people who took the survey. But for this, I'm really going to focus on -- our analytic sample was just the 3,878 folks who reported ever using e-cigarettes.

Just some selected weighted characteristics: 10% were nonsmokers; 19% were former smokers; and 71% were current smokers. As I mentioned, everyone in this sample had reported at least trying e-cigarettes once. But among those people, 65% said that they no longer used them. So I'm going to refer to those people as either former users or having stopped. And 35% said that they still used e-cigarettes some days or every day.

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This is a huge long list of reasons that we allowed people to endorse for reasons why they first tried. I'm not going to read them to you or ask you to read them. I just wanted to point out that they fall into two buckets. So the first bucket are not goal-oriented reasons; so this is curiosity, the recommendation of a friend or family member, the appeal of advertising, or simply I don't know.

Then there was a whole longer list of reasons that were goal oriented. So people were trying to achieve a certain outcome like quitting or reducing smoking or improving their health or saving money. So we asked this in a check-all-that-apply format, and then we asked them to pick a main reason. We used a similar format for reasons for stopping among those who no longer used, and I'll show you those items later.

So if you look at the top reasons that people said that they first tried, again, I'm not going to read these all to you. I just want to point out the top five. So curiosity was far and away the most commonly endorsed reason for trial at 53%. Then you jump down quite a bit, and you see recommendation of friend or family, to quit or reduce smoking, to reduce harm, and to use in smoke-free places. Now, you'll notice that the top two here are not goal oriented, and the

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ones below that tend to be goal oriented, so I'm going to come back to that later.

As I said, two-thirds of people said that they had tried but no longer used e-cigarettes, and the most common reasons for stopping, the main one was people said I was just experimenting, so you sort of got this match here between the most common reason people said they tried was that they are curious, and the most common reason that they stopped was that they were just experimenting in the first place. And after that, we've got didn't feel the same as smoking, taste, cost, and I don't know.

Now, we noticed an interesting pattern here. When you looked at the main reason that people reported trying and then whether or not they continued to use, so if you looked at just those people whose main reason for trying was not goal oriented, most of those people were no longer using. But if you look at people who were goal oriented, they were trying to achieve a certain outcome, and they said that was their main reason, those people mostly continued to use. So looking at some specific numbers, if your main reason was curiosity or recommendation, 69%, 68% of those people stopped. If your main reason was to quit or reduce smoking or to reduce harm, only

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about half of those people stopped. The rest were still using some days or every day.

So some take-home points first here: Curiosity is a major driver of first trial. I think in research we sometimes like to think of everything happening for a reason, that people are always trying to achieve goals. But, in fact, often people try because they're curious and the product is there, and they just want to know what it's like.

Second, most people who try an e-cigarette do not appear to go on to become every day or some day users, so there's a lot of experimentation, there's a lot of kind of one-off use, and I think we need to keep that in mind. And, finally, this kind of data suggests that there might be different, sort of, types of users, so there might be people who are these casual experimenters who typically stop using and committed users who try for a reason and then often continue to use. Now, one thing we don't know is whether they continue to use because they achieved those goals or because they're still trying to achieve them.

So this is a point that we've talked about a ton today. Most studies are cross-sectional; we need some longitudinal data in order to establish causality. These are self-report

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measures which may be sort of the best we can do when we're looking at things like reasons, but they are subject to bias, and that's important to keep in mind. And, finally, there's just a ton of variation about what kind of -- by what kind of, sort of, response options you give people. So curiosity is the main one that comes out there. Really highly endorsed, but if you don't ask, that's not what people are saying.

So going back to my original point about whether there might be a link between motivation and behavior. I think my study suggests sort of, in a preliminary way with, again, cross-sectional data, that there might be a link here, that the reason that you try, whether or not it's goal oriented, is linked to whether you continue to use. And other studies have shown this as well. So Rutten and colleagues did a large nationally representative survey, and they also noticed some patterns that related reasons to behavior. So, in their case, when people said that they tried in order to quit smoking because the product was cheaper or they wanted to reduce their stress, people who endorsed those reasons were more likely to reduce the number of cigarettes they smoked, whereas people who tried because of curiosity were less likely to reduce the number of cigarettes they smoked.

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We certainly need better measurement and longitudinal studies. Again, I'm not telling you anything you don't know there. It is really hard to capture this stuff because the field is changing so quickly, and it's going to continue to change. And I think people's reasons will change as, you know, new policies happen and the environment changes. We need to be looking at other populations, so youth, there have been some nice studies of youth I think we're going to hear about later. Non-tobacco users.

And, finally, dual users, which is an area I'm really interested in because I think it sort of threatens to undermine some of the ways that e-cigarettes could be helpful for public health. And, finally, I do think this research has some suggestions that there are different user types. And there's sort of a "so what" point there. And I do think it matters because if there are different user types, it's possible that they will respond differently to policy. So, for example, people who try because of cost might be more sensitive to changes in policy-related taxation, or they might be very differently sensitive to intervention, so it may be that people who try because they're curious respond really differently to messages that we put out there than people who try because they

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want to quit smoking. So I think this is a really fascinating area for continued research.

Thank you so much.

(Applause.)

DR. DRESLER: Thank you.

And our next speaker is Dr. Suchitra Krishnan-Sarin from Yale University, and she will be speaking on Use, Appeal and Access to E-cigarettes among Youth.

DR. KRISHNAN-SARIN: Thank you. And good mid-morning to you all. So I'm going to walk you through some of the evidence that we have been collecting in Connecticut, and you saw some presentation of this earlier already.

This is our group. It takes a village, and we have a village to get all this work done. I could never have done any of this work without all the individuals who are depicted on the slide, and also funding from NIDA through our Yale TCORS and other center grants.

So I'm going to show you data from three waves of surveys that were conducted in Connecticut. The first wave was conducted in November 2013 and included two middle schools and four high schools, representing four out of nine district reference groups in Connecticut. District reference groups,

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for those of you who are not familiar with what those are, they are -- the entire state is broken up based on socioeconomic status and needs. And Connecticut has nine of them, so we selected schools from four of the nine district reference groups.

Wave 2 represents five out of nine district reference groups, and five schools were actually longitudinal, so we collected data, again, from the same schools in Wave 2. And now we are recently completing Wave 3, which is going to have even more longitudinal data. And we linked these samples using self-generated data identification codes, which adolescents generate themselves during the survey.

These are whole school surveys. Study procedures are approved by the Yale IRB and participating schools. And we use passive parental permission for all our surveys and, of course, participants are informed that the survey is anonymous.

So the first question. I'm going to walk you through a series of questions now that we asked of this -- and, of course, there's a lot more we can ask. The first question is: Are adolescents using e-cigarettes? I will not spend too much time on this because you've already seen some excellent data on this issue. But this is our Connecticut data, and I'm going to

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walk you very briefly through this slide.

The first panel is have you ever heard of e-cigarettes? And there are three groups, three categories here. The blue is the never cigarette smokers; the yellow are ever cigarette smokers; and the green are past 30-day cigarette smokers.

So we are showing you whether they've heard of e-cigarettes, whether they've ever tried e-cigarettes, and past 30-day use of e-cigarettes in these three groups of adolescents. And the top panel is high school, and the bottom panel is middle school. If you want more data on this, this is in press, and you can find it online. But, essentially, the take-home point from this is that yes, use rates are high, and they have been climbing ever since we have been monitoring since 2011.

And I will just focus on one point, which is that the past 30-day use of e-cigarettes amongst kids who are already smokers, it's very high at 64% and 40%, but I will also point out that the kids who are classified as ever cigarette smokers are those who say we tried cigarettes in the past but I'm not currently using cigarettes. So these are the kids who may have tried cigarettes at some point in their lifetime but currently are not using cigarettes. And you can see that the rates of

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use of e-cigarettes even amongst this group is pretty high. We also wanted to ask the question: Amongst those who are reporting past month use of e-cigarettes, how many days do they use e-cigarettes?

And this gives you, again, the breakup; it's broken up exactly the same way. The white is middle school; yellow is high school; and you have the three categories, which is never smokers, ever smokers, and current smokers, the three groups there. And you can see that the days of using in the past month are not small, so they are not like they're saying I'm using just on 1 day a month. The days of using are pretty much up there. They are between, you know, 10 and 12 days in the past month that they report they have used e-cigarettes.

The next question we asked is: Are adolescents who have never used e-cigarettes susceptible to future use of e-cigarettes? So consider kids who say I have never tried an e-cigarette. And for this, what we did -- oh my gosh, I don't know what happened there. It must have been some mess-up in the transfer, I'm sorry, on the bottom half of that slide.

For this we used a peer susceptibility scale. For those of you who are familiar with that, it consists of questions which ask kids about would you try a cigarette in the future,

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would you try a cigarette if somebody offered you a cigarette. We adapted those for e-cigarettes, and this is showing you -- and we call it an e-cigarette susceptibility scale. And this is e-cigarette susceptibility among never users.

I'm going to break down the groups for you, and I think it's very similar to the earlier panel you saw. The first bars are probably the total sample; the second bars are probably the never smokers. Then you have the ever cigarette smokers, the ones who have tried cigarettes in the past. And the last bar is the cigarette smokers. So take-home point again: e-cigarette susceptibility is also high.

This panel shows you a comparison of cigarette versus e-cigarette susceptibility amongst those who have never tried e-cigarettes. So we asked both cigarette susceptibility questions and e-cigarette susceptibility questions amongst this group. So these are kids who have never tried e-cigarettes or cigarettes. And essentially what you see is that even amongst those groups of kids who are potentially susceptible to future use, cigarette susceptibility is actually lower in 2013 than e-cigarette susceptibility.

The next question we asked is: Are adolescents reporting that they are starting tobacco use with e-cigarettes? Now, for

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this we used our survey data, again, and what you see here is predominantly middle school students mostly say that they started with e-cigarettes, almost 50% of middle school students. Now, a caveat I would like to point out is that this is a small sample, so not that many kids are endorsing this, but it's still something that we need to keep in mind and monitor. Now, we wanted to ask this question another way and we wanted to see if cigarette smokers, if they endorse e-cigarettes for the first tobacco product that they started with. Now, please keep in mind these are all cross-sectional data. I'll show you some longitudinal data soon, but you have to keep all these caveats in mind when you look at this.

This is the slide which shows you the cigarette smokers who reported that e-cigarettes were the first tobacco product they used. What you have on the left is ever cigarette smokers, so these are kids who have tried a cigarette. And on the right, you have smokers who say they have smoked greater than 100 cigarettes in their lifetime. And we asked them: What is the first tobacco product you used? And about 40% of ever cigarette smokers and about the same of smokers who had smoked greater than 100 cigarettes in their lifetime said that e-cigarettes were the first tobacco product they had used.

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Again, with all the caveats, cross-sectional, self-report data.

Now, let's get to some data that I'd like to show you from our longitudinal findings: What factors predict longitudinal increases in e-cigarette use? For this, as I said, we used data that we collected in November 2013 and used a matched sample that we also assessed in June 2014, and what you see here is a breakdown of how that matched sample was, you know, what the use patterns were. In November 2013, out of the 2,000 or so students who are matched, 84% were never e-cigarette users, and 16% were ever e-cigarette users in the sense that they had tried an e-cigarette once, at least. And then in June 2014, we looked to see what happened to these patterns of use. Amongst the 84% of never cigarette users, we actually had an emergence of trying e-cigarette behaviors in about 10% of the sample, which is the second panel you see on the June 2014 area. And then amongst the ever cigarette users, about 41% of them said that they had started more current or past month more regular e-cigarette use.

In our predictor analysis, here are some of the predictors of e-cigarette initiation: being older, being susceptible to e-cigarettes, lifetime cigarette use, and disagreement with perceptions that e-cigarettes are harmful to health, and

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agreement with the perceptions that e-cigarettes are safer than regular cigarettes. So these are some of the predictors which came out in our analyses.

Now, let's move on to another area, which is: Why do adolescents use e-cigarettes? And this data is also in press, but what you can see here is these are -- we asked the adolescents, middle and high schoolers, why did you initiate e-cigarettes, and these are some of the questions, and they could pick all that they wanted, all the reasons they wanted. And these are some of the reasons they picked. And as you can see, some of the primary reasons that stand out, again, curiosity, as was just mentioned; and also good flavors; the perspective that it is healthier than cigarettes; and a variety of other reasons which range from doesn't smell bad to families using it and parents using it and so on and so forth.

Now, we are very interested in monitoring flavor preferences in kids because flavors seem to be a big reason for why kids initiate e-cigarettes. This is just a graph of flavor preference profiles amongst kids broken up by those who are either lifetime or e-cigarette users in the sense that they have tried an e-cigarette at least once, those who have used e-cigarettes in the past 30 days, or those who are dual users,

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and the only take-home point here is that fruit flavors are predominantly preferred by most kids.

Now, I had one more slide I wanted to show you here that unfortunately I left out, and I just want to make a point of telling you about this. We also asked the adolescents what is cool about e-cigarettes, and of course, flavors was one of the top reasons, the top things they said is cool about e-cigarettes. But the other thing which is very popular with e-cigarettes right now is smoke tricks. Smoke tricks are extremely popular. Kids use e-cigarettes and share use of e-cigarettes for the ability to do smoke tricks. And for those of you who know the components, it's related to the vegetable glycerin that's there in the product, and therefore, they can use it to do some really cool things.

It's like their version of bubble gum, what bubble gum was for us when we were growing up, although I could only blow a bubble. I couldn't do anything more than that. So we also asked the kids: Would you try an e-cigarette if it only came in tobacco flavor? And this is all the participants, and what you see here is predominantly, most participants say probably not or definitely not to this question, would they try an e-cigarette if it only came in tobacco flavor.

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Now, let's move on to a few other points: Where do adolescents get their e-cigarettes? These are some of the sources of procurement. Again, I'm so sorry that the slide is messed up at the bottom. But predominantly they get it from their friends, girlfriends, boyfriends, and from a variety of other sources. And if you want more details, I can give you more details later. I'm sorry, I can't read this myself. I don't know how it breaks up.

We asked the kids: Have you ever tried to purchase an e-cigarette? And 50% of them said they had never tried to buy an e-cigarette, which means they were probably getting it from other sources like their friends, like their parents. However, a percentage of them also said they tried to buy it from an online store; online stores are very popular. A percentage said they tried to buy it from a physical store, and a percentage said they had tried to buy them from both places.

And we asked them: Were you ever refused sale from a physical or online store? And, unfortunately, only a small percentage of the kids who said they had actually purchased a cigarette from a physical or online store said they were actually refused sale, especially from online stores.

And the final point I want to go over is: Where do

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adolescents use their e-cigarettes? This is a graph showing you the location of e-cigarette use. Predominantly, most of them use it in their homes. A lot of them use it in public places where smoking is not allowed or in school, and in a variety of other places as you can see on this graph.

And we also asked the kids: Would you try an e-cigarette if it could not be used indoors? And this is the percentage of participants who said no. You see here predominantly a lot of the kids said they would not use it if it could not be used indoors. Of course, the percentages are lower for those who are current smokers, as you see in the purple bars, are current e-cigarette users. However, predominantly most of them said they would not use it if it could not be used indoors.

So what does this tell us overall? I've shown you a lot of data. I would just like to say that there's very high awareness of e-cigarettes among youth. Use rates are increasing exponentially. It appears that even nonusers are highly susceptible to future use, and that the high appeal is related to availability of flavors and the novel nature of these products, like the ability to do smoke tricks.

And I just want to end with some critical implications that could be -- that some of our findings might have to

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helping to reduce adolescent e-cigarette use. We definitely need to regulate the product to reduce appeal to adolescents, whether that means controlling flavors, removing flavors; whether that means preventing the ability to do smoke tricks; whether that means preventing the ability to manipulate the product.

We have to reduce appeal for adolescents. We have to establish and monitor local and federal policies to prevent access to minors and restrict use in indoor locations and schools. Many states, many locations still do not have these policies, and kids can still use them in a variety of places.

And I think very importantly, we need to establish educational and prevention programs that present accurate information about e-cigarettes, not just directed to the kids but also directed to parents, because if you remember, a lot of use was in the home. So we look to make sure that we make parents aware of the influences of this product and how their kids should not use them so they can also have control over their use behaviors.

And I'd like to stop there.

(Applause.)

DR. DRESLER: Thank you.

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Our next speaker is Dr. Jennifer Pearson from the Schroeder Institute for Tobacco Research and Policy Studies at the Legacy foundation speaking on E-cigarettes and Smoking Cessation: Insights and Pitfalls from Observational Studies.

Jennifer.

DR. PEARSON: All right, good morning. And I'd like to thank FDA for asking me to speak today. I will present lessons learned in the process of analyzing observational studies from a secondary data source to understand the relationship between e-cig use and cessation. Please note that Legacy is submitting extensive written comments that will give a much deeper dive into the topics that I am touching upon today. So here are my disclosures.

So this figure shows the change in prevalence of lifetime e-cigarette use among U.S. adults by cigarette-smoking status. While the prevalence of lifetime use among nonsmokers, the green line, has remained essentially flat and has increased somewhat among former smokers, the prevalence of lifetime use is highest among current smokers.

Why are smokers so attracted to e-cigarettes? As Dr. Jessica Pepper has discussed in her presentation, the most common reason for e-cigarette use is as a cessation aid. As

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yet, we do not have U.S. national data on the prevalence of using e-cigs to quit, nor do we know their popularity as a cessation aid relative to other aids. However, British data from the Smoking Toolkit Study suggests that e-cigarettes, the thick green line, have recently surpassed over-the-counter NRT, the pink line, as the most popular smoking cessation aid in England, with 30 to 35% of smokers reporting use of e-cigarettes to quit between spring 2013 and January 2015.

Given the clear appeal of e-cigarettes as cessation aids, what we really want to know is what is the effect of e-cigarette use on cessation? Typically, we address the efficacy of a smoking cessation treatment with randomized controlled trials.

Well, a few RCTs, namely Bullen et al. and Caponnetto et al. have shown promising results. They are imperfect, employed devices that are now outdated, and are few in number. In a funding environment in which we are unable to conduct large-scale rigorous RCTs, we are left with interpreting conclusions from the 13 observational studies published in this area. However, all of these studies suffer from shortcomings that limit our ability to make inferences about the effectiveness of e-cigarettes for smoking cessation.

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This was the motivation for this paper, which my colleagues and I published in late 2014. The goal of this paper was not to answer the question are e-cigarettes effective cessations aids, but to highlight the methodological and analytical challenges to answering this question using observational data, and suggests how this area of research could be improved. Like most of the observational studies on this topic, this was a secondary data analysis.

The sample was comprised of over 2,000 participants with complete 3-month follow-up data. Our exposure was e-cigarette use for cessation measured retrospectively at the 3-month follow-up, and our outcome was 30-day smoking abstinence, also measured at follow-up. We assessed other sociodemographic, psychosocial, and tobacco use history characteristics, including the use of other smoking cessation aids at baseline and follow-up.

In this talk, using examples from our research and the published observational literature, I will highlight three problems that are common in observational inquiries of the relationship between e-cig use and cessation: namely, imprecise measurement of the exposure; the potential for unaddressed selection bias; and, finally, variability in how smokers use

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e-cigs and what devices they employ.

The first problem was extremely common in the published literature at the time when my colleagues and I began our analysis, namely, imprecise measurement of the exposure or e-cigarette use for the purpose of cessation. There are two aspects of this measurement error that I would like to highlight. The first is not specifying the reason for e-cigarette use.

If we want to answer the question of whether e-cigarettes affect cessation, it is essential to measure the actual exposure, which is e-cigarette use for cessation rather than any e-cigarette use. While smokers use e-cigs to quit, there are also many other reasons why people use these products. As has been highlighted by Dr. Pepper, differentiating motivated users from casual experimenters will better inform our understanding of e-cig use and cessation.

Most of the observational studies linking e-cig use and cessation don't assess why smokers are using e-cigs. They simply ask about any or past 30-day use and correlate that with cessation, conflating use for cessation with use for any number of other reasons. Without better assessment of the exposure in these studies, it is impossible to infer the relationship

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between e-cig use and cessation. This problem is easily addressed, however; simply ask a smoker their primary reason for e-cigarette use. In our study we presented participants with a list of common quit methods, including e-cigarettes, and asked them which methods they had used in the past 3 months.

Another source of error in the existing studies is the lack of precision in associating e-cig use with the most recent quit attempt. This level of precision is important for two reasons. First, recall bias is a serious threat to validity in population-based surveys of cessation behavior. Paraphrasing Dr. Saul Shiffman's 2008 publication, past quit attempts are often undertaken spontaneously, are short-lived, and are easily forgotten. Asking about the most recent quit attempts cues participants to report the most recent and perhaps previously forgotten quit attempt rather than the most salient attempt. The second reason why timing is important is the presence of the black box. E-cig use may not have much bearing on an individual's current smoking status if the e-cig was used in conjunction with other aids or was used previously in an earlier quit attempt which was perhaps initially successful but ended in relapse.

If we want to understand how e-cigs and cessation are

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related, then we need to gather as much information as possible about the quit attempt that led to the individual's current smoking status. This is an area of significant improvement in the future as only one study, Brown and colleagues, associates e-cig use with the most recent serious quit attempt.

The second problem that we identified was that e-cig users are different from nonusers at baseline and when measured at follow-up. Research suggests that smokers who use e-cigarettes to quit consume more cigarettes per day, have higher nicotine dependence, make more quit attempts, make longer quit attempts, and use more cessation aids than smokers who did not use e-cigs to quit. Most of these characteristics are associated with poor cessation outcomes, so it's not surprising that smokers who use e-cigs have poor cessation outcomes. We may be comparing apples and oranges when we try to compare these two groups. Smokers who use e-cigs to quit are using them not just to quit, but to quit because they have had a harder time quitting in the past.

In our study, we saw that at baseline, e-cig users smoked more cigarettes per day, were more likely to make a quit attempt in the past year, had higher Fagerström scores, and had a higher prevalence of past use of e-cigarettes.

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Knowing that selection bias was a possible factor in previous studies, we decided to use an analytical approach called entropy balancing to render the characteristics of the groups who did and did not use e-cigarettes more comparable. Why do we use entropy balancing rather than regression? Regression is commonly used to control for confounders, but it is imperfect.

While adjustment for other variables is possible using regression techniques, this approach is unable to account for any unmeasured variables that might further affect selection into one group or another. There are many different analytical approaches to addressing potential selection bias. With all of these approaches, the goal is to address a lack of randomization to the exposure and get us closer to comparable groups so that we are no longer comparing apples and oranges, but perhaps red apples and green apples. With approaches like entropy balancing and propensity score matching, the two groups will still not be identical, but they will be closer than they previously were. In the interest of time and to avoid further boring the audience, I'm not going to go into more detail about entropy balancing. I'd direct those of you who are interested to our publication for in-depth discussion of the method, its

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strengths, and its weaknesses.

Another source of error is lack of information on other cessation aids, either used concurrently with the e-cigarette, before the e-cigarette, or between the e-cigarette, and the smoking status at the next observation point. Our analysis revealed that smokers who use e-cigs to quit in the past 3 months reported higher prevalence of nearly every other cessation aid, including prayer.

Smokers were using e-cigarettes to quit as part of a kitchen sink approach to quitting. This kitchen sink approach highlights the importance of asking about use of other cessation aids in observational studies. However, while asking about other aids might give you more information about how smokers are really trying to quit, without asking specifically about the most recent quit attempt, we can't be sure if the e-cigarette preceded, co-occurred, or followed the use of other aids. This poses a serious challenge to statistical modeling and was the motivation for presenting multiple approaches to the analysis in our publication, as seen here.

Since we don't know what's going on in the black box or even the order of the blue and black boxes, we ran a number of models that had different underlying assumptions. We found

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that the interpretation of the results differs according to what we included in the model and the assumed order of the quit methods. As we moved from unadjusted regression to regression adjusted for sociodemographic and tobacco use history, we saw little change in the odds ratio.

Inclusion of other quit aids attenuated the relationship between e-cig use and cessation. Entropy balancing without adjustment for other aids resemble the adjusted logistical results. However, inclusion of other cessation aids in Model 5 showed no relationship between e-cig use and cessation. The point of this table is not to suggest that one of these odds ratios is the truth. The point is to show that the results change base on the analytical approach, what is measured, and how it is measured. Researchers need to account for potential selection bias in studies such as these, critically think about how e-cigarettes are being used in concert with other aids, and make sure that we are appropriately modeling complex cessation behavior given the underlying assumptions of the analytical approaches we employ.

For the final section of my presentation, I will highlight how unmeasured differences within the group of e-cigarette users may affect our ability to understand how e-cig use and

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cessation are related. The problem lies in assuming that all e-cig use is alike. E-cigarette users are different from each other in at least two ways.

First, e-cig users are different from each other in how much they use their devices. We must therefore assess the dose of e-cigarette use. Second, e-cig users are different from each other in the characteristics and performance of their devices. This is especially important given how quickly devices are changing.

So let's return to dose. Most published observational studies imprecisely measure the exposure, conflating occasional with daily e-cigarette use. Six studies ask about any use in the past 30 days, while four studies equate lifetime e-cigarette use with cessation. This is the equivalent of asking someone if he had ever taken aspirin, even once, then associating his past 30-day headache status with lifetime aspirin use.

My colleagues and I highlighted the importance of assessing dose in our manuscript hypothesizing that more e-cigarette use might correlate with better outcomes. And indeed, during the review process for our manuscript, a paper was published showing just that. Drs. Biener and Hargraves'

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paper revealed that the intensive e-cigarette use, meaning daily use for at least a month, was associated with a six-fold increase in the odds of smoking abstinence. On the other hand, there was no difference in cessation for intermittent users.

And the final problem I'd like to highlight was the lack of measurement of e-cigarette device type. As this graph from Farsalinos and colleagues shows, nicotine delivery varies by e-cigarette device type. We know from surveys of exclusive e-cigarette users that the majority of vapers use open devices with large batteries, suggesting that these devices are better at satisfying nicotine withdrawal than their cigalike counterparts.

And, in fact, when device type and frequency of use is assessed, we see that both of these are important in understanding how e-cigarette use might affect cessation. Dr. Hitchman and colleagues showed that compared to respondents who reported no e-cigarette use at follow-up, the odds of cessation were lower among respondents who use cigalikes non-daily and higher among respondents who use tank devices daily.

There is no relationship between daily cigalike use and non-daily tank use and cessation. As other researchers have suggested, it is possible that cigalike and open tank systems

have different effects on smokers' behavior and thus have different effects on public health. To understand the effect of these devices all in tobacco use behavior, it is essential thus to measure device type.

So, in conclusion: Evaluating the population level effectiveness of e-cigarettes for cessation or indeed any cessation treatment is fraught with difficulties. Conclusions from observational studies of e-cig use and cessation vary widely depending on what is measured and the underlying assumptions of the analytical approach. Our critical engagement with the literature suggests that observational studies of e-cigarette use and cessation are uninformative, give an imprecise measurement of the exposure, and the potential for selection bias. Because of these drawbacks, we need to be extremely cautious when drawing conclusions from these studies about the efficacy of e-cig use for cessation.

I hope my talk this morning has convinced you that the status quo approaches to the measurement and analysis of e-cig and other tobacco use behavior are no longer sufficient in the current complex behavioral and tobacco product environment. To truly understand the impact of e-cigarette use on cessation, we need to precisely measure the why, how, and what of e-cigarette

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use. We can make great strides in this area by standardizing how we measure the exposure.

Standardization of these measures will allow comparisons across studies, something that is extremely difficult at this time due to the heterogeneity of the measures and study designs in existing studies. We need to be extremely careful when quantitatively synthesizing studies from this area in meta-analyses. Observational studies will always be limited and at best hypothesis generating. These studies can tell us how people are using their products in the population, but we won't get at the strict causal effect of e-cigs on cessation. We need randomized controlled trials to answer this question. Until such designs are possible, better designed observational studies and randomized effectiveness studies will be needed to inform FDA CTP's understanding of how e-cig use is associated with cessation.

The end.

(Laughter.)

(Applause.)

DR. PEARSON: There's lots of references at the end. I give up.

DR. DRESLER: Yeah. No, no. I'm sorry.

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DR. PEARSON: I think the battery might be dead.

DR. DRESLER: Yeah. No, no. There's -- it's multi-system.

DR. PEARSON: Or I killed the --

DR. DRESLER: It's a good slide to end on, though.

DR. PEARSON: Yeah.

DR. DRESLER: Thank you.

Our next speaker is Dr. Saul Shiffman from Pinney Associates and the University of Pittsburgh, speaking on Flavors in E-cigarettes: Promise or Peril?

DR. SHIFFMAN: I thought I would abandon my planned remarks and explain entropy adjustment to you.

(Laughter.)

DR. SHIFFMAN: And then I realized I don't know what it is.

So here are my disclosures. I and others at Pinney Associates consult to Reynolds American on these sort of products. And I'm going to be presenting data from a study that was sponsored by NJOY, which is also an e-cigarette manufacturer. However, I'm not here speaking on behalf of either of those, and in fact, neither of them has seen, much less had any comments on, my remarks.

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I want to start with really big picture framing because it affects how we approached our study. So it is important to get the basics of the logic of harm reduction, and we start from the premise that smoking is killing half of continuing smokers. That's what we're responding to. And as David Abrams emphasized, it's really combustion that's at the heart of this. And so the point isn't that alternatives need to be completely safe -- you know, nothing is completely safe -- but rather that they need to be substantially safer, and this isn't that hard to get. There are lots of examples of harm reduction, both the things we think of as harm reduction, like methadone for heroin addicts -- no one claims methadone is safe and should be put in the water -- but also things which we perhaps don't think of as harm reduction, like vaccines and medicines which do harm some users but we look at the net effect overall.

Now, the act under which FDA is considering regulation sets out a very important standard, which is the idea that what we ought to be attending to is the impact on the population overall. So, again, that gets us to not perfection, but rather improvement in the current state of affairs. And really a matter of balancing risks and harms, not assuming that there are no harms but importantly balancing them. It's a kind of

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utilitarian calculus. And, importantly, the risks and harms may be distributed in different populations, and that's very important.

So there are many population segments. Our study focused on the two that we regarded as the most extreme and therefore most interesting. On the one hand, adult continuing smokers -- those are the people who have a 50% chance of dying because they're smoking -- have the greatest potential benefit, and therefore, the benefit is maximized if they adopt e-cigarettes. It does nobody any good if they're not using them. And so to the extent that flavor would help increase the appeal, that's a good thing for public health. And indeed, my colleague Jack Henningfield has pointed out that it might enable these products to be appealing with less nicotine by giving this kind of sensory appeal.

Conversely, in teen continuing nonsmokers, there's no promise of benefit, there's only risk of harm, and so that's where you want to really minimize or completely eliminate use and therefore minimize appeal. And that's the context in which we want to look at flavors. And there's been the thought that certain flavors or flavors in general differentially attract teens; that would clearly be a bad thing because we would be

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promoting use where there's harm rather than where there's benefit.

So, in our study, what we did is contrast the appeal of flavors in those two, if you will, extremely contrasting populations. Like about half the research you've heard this morning, it was -- the samples were drawn from a web-based panel: 216 non-smoking teens who had not engaged in tobacco use in the last 6 months and no e-cigarette use, and then 432 adults who had been smoking at least 3 years.

And our design was, since we're simple folks, pretty simple. We presented those flavors, or flavor descriptors really, and asked them to rate their interest in using an e-cigarette of that flavor. However, a twist was that we also asked them to rate their interest in using two other non-tobacco products with roughly the same range of flavors, and we had two motivations.

One was we didn't tell subjects either when they enrolled or as they were going through the study that our interest was really in e-cigarettes, so it helped us mask the purpose of the study. But it also allowed us to determine, if you will, the assay sensitivity of the study; that is, could we see some differentiation by flavors if we look outside of the tobacco

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area, and we'll see that turned out to be very important.

These are the flavors that were tested, and there were three in the lower left that we included kind of deliberately, provocatively, not because we thought those were appropriate flavors, but because they are actually out there, and they're the kind of flavors that generate revulsion about offering such flavors. And you can see the range of the others.

So I'm actually going to start by presenting you the data on the non-e-cigarette ratings. Remember, this is ice cream and bottled water. And I'm going to show you the teen data for a particular reason. And what you see, which are not terribly surprising, is that (a) teens have relative interest in ice cream and bottled water. They're more interested in ice cream than bottled water. If you have children, this will not come as a surprise to you. But they also differentiate by flavor, and they differentiate flavor by product. So vanilla is a very attractive flavor in ice cream; it is not -- it is the least attractive flavor in bottled water. So the point is that this method is capable of detecting variations by flavor and flavor by product.

So now let's look at what these same teens said about these flavors in e-cigarettes. And basically what they said is

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not interested. So you can see that the average ratings were very near zero. It's been suggested we had floor effects, which perhaps we did. Maybe they wanted to rate them negatively, but they're near zero, and there is no statistically significant variation by flavor. In other words, they're not interested, and it doesn't matter which flavor you tell me, I'm equally not interested. And Dr. Pepper has actually, in a very different design and with a very different sample, similarly shown in a sample of males that offering flavors made no difference.

This is now what the adults say, the adult smokers, important to keep that in mind. What you can see -- well, first of all, let me point out to you that I've expanded the scale so you can see the differences. But what you see is that they are considerably more interested in e-cigarettes overall, and in fact, there is a very significant difference by flavor.

I will say that they are more interested in e-cigarettes regardless of flavor. In other words, for every single individual flavor, the adult smokers have greater interest. But the important point is that they do care about the flavor, and I will come back to that a little bit to talk about who it is, which of those adult smokers most care about flavors.

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There's sort of a puzzle here because you've seen data from Suchitra, you've seen data from others that, in fact, some of the teens who are using e-cigarettes are using flavors; so how can it be that we're saying they have no appeal and yet they're using those? And the key point is it's not the same individuals. Remember, we studied teens who are not smoking, and in fact, there's literature already showing that response to flavors differs with smoker characteristics.

So this is a study by Manning et al., and it was done -- they showed -- they had three different brands that she showed teens, either one that was cherry with appropriate graphics or one that was plain flavor. And what they found, which they had predicted, was that teens who are low in sensation seeking, who are not thrill seekers, risk takers actually reacted more negatively when they were offered a flavor.

The teens who were high risk takers were the ones who reacted positively to flavor. In other words, again, it splits by the teens who have the sort of characteristics that lead people to smoke are the ones who are attracted to flavor, so no surprise that these teens who are smoking or destined to smoke are attracted to flavors, as we see from the behavioral data, and that's perfectly consistent with the fact that the teens

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who are not smoking are not attracted to flavor, and this fits into a lot of what you've heard already. I was hearing the Monitoring the Future data for the first time, which is these are different populations. Teens don't decide to smoke at random. Those are the teens who are thrill seeking, who will try anything, who use drugs.

In the Wills, which you heard about briefly, what they saw was that e-cigarette users and smokers were very similar to each other on self-control, dis-regulation, peer smoking, and both were very different from nonsmokers. In other words, smoking is not randomly distributed.

It collects among teens who have these particular characteristics. So we shouldn't expect that their responses, even to something like flavors, are going to be the same. So I think every -- almost everyone has said this, but it's important to keep in mind, it's not the same individuals.

I want to come back to the adults in whom you saw greater interest but also greater interest in flavors or greater differentiation. And that turns out to be very important. In adult flavors, in adult smokers, there's some indication, although we've heard that flavor may be related to curiosity and initial appeal, that it actually has almost the opposite

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relationship, that flavors become more interesting as people progress down a journey of shifting from smoking to e-cigarettes, and that the adoption of flavors is part of a pathway for some people away from combusted cigarettes toward e-cigarette use. And let me show you how our data suggest that, and then I'll show you some other data.

So among the adult smokers, we differentiated by people who had never used an e-cigarette; past use, which meant you said I tried it once but I haven't used it in the past 30 days; and recent use, which was past 30-day. As you've heard from others, we're reluctant to call that current use because since there's so much trial and so little adoption, past 30-day use may just be another measure of trial.

But what you can see is that consistently the current users, not surprisingly, are most interested in e-cigarettes; that's kind of tautological. But also they make the most differentiation by flavors. And, in fact, really, the never users do, they still have a significant differentiation by flavors, but much less so, and the kinds of flavors are very different. So vanilla bean is actually the top non-tobacco flavor of interest to current or recent e-cigarette users.

The meaning of this and its importance is brought out

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better in a study by Farsalinos, and what he did is survey current e-cigarette users, and he divided them into those who were current smokers and who were no longer smoking, and he also asked them again, retrospectively, what was the flavor that you started when you started using e-cigarettes and what's the flavor that you're using now. So it gives us, in a retrospective way, a sense of the developmental trajectory both over time but also with respect to whether it results in quitting combusted smoking or not.

My summary of his results and what I'm showing you is the net difference between what people said they started with and what they're using now. And what you see -- let me see if I can use the pointer -- is that as people progress, the big picture is that tobacco flavors decline pretty steeply, and basically just about every other flavor increased. So over time, people are migrating from initially using tobacco flavors, which makes a lot of sense, people start using something that seems familiar, but that they then progress to other flavors. And, in fact, in qualitative work, what you see is people say once I was moving away from combusteds and towards e-cigarettes, I didn't want the reminder of smoking. I want this to be different. The other thing that you see is the

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decline in tobacco flavors is particularly steep among those who have stopped smoking. So it suggests that the migration from tobacco flavors to other flavors is part of a trajectory away from smoking towards substituting e-cigarettes.

I'm not going to spend a lot of time here. We've heard a lot of methodological discussion. Certainly, the study had limitations; not suggesting this is the be-all and end-all study. We can have lots of methods discussion.

I want to come back to the big picture in terms of the role of appeal in public health. Maybe this is too simple, but sometimes we seem not to get it, that a harm reduction product that we make sufficiently unappealing that nobody uses it has no positive public health impact. It has to -- the impact is proportional not only to the harm reduction, but also to the adoption in the population. And so appeal to the right target population and avoiding appeal to the wrong target population is a public health good. And appeal, I have focused on flavors, but there are lots of other things: convenience, cost, et cetera. And this is really a familiar theme for me. I spent some good 20 years trying to encourage smokers to use FDA-approved smoking cessation products containing nicotine to quit smoking, and what we discovered is they just weren't

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appealing enough.

And so the Robert Wood Johnson Foundation founded a workgroup that worked on consumer demand, and it seems to me that what they said there applies equally here, which is that we need to think about what are the needs and wants of our target population and how do we design products that people actually want to use. And for me, having spent 20 years pretty unsuccessfully trying to encourage people to use smoking cessation medications, the idea that smokers are actually lining up and paying their own money for a nicotine product is revolutionary and something that we ought to be promoting.

And, finally, I want to remind us both what the Act says and what the Center for Tobacco Products has said about the basis of regulation, which is that it needs to be based on science and research. And I say that because we all have intuitions about flavors, but intuitions don't count; data does.

Thank you.

(Applause.)

DR. DRESLER: Thank you.

And our next speaker will be Dr. Youn Lee from RTI speaking on Patterns in Use Behaviors across Electronic

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Cigarette Device Types.

Dr. Lee.

DR. LEE: Hi. My name is Youn. Most people call me Youn Ok, and I'm from RTI, and I'm going to talk to you about the characteristics of users and their behaviors across e-cigarette device types.

So I'd like to acknowledge our funders and note that we have no conflicts to disclose.

And so it goes without saying that e-cigarette use in the U.S. is increasing. However, little is known about the specific device types or use behaviors that might characterize these trends. One reason for this is that the current e-cigarette marketplace is highly diverse, as reported here, by Shu-Hong Zhu and colleagues. There were 460 different brands of e-cigarettes available. But there are also various types of devices. They refer to these in their article as cigalikes, eGos, and mods, noting that some devices are being sold as e-hookahs or designed to resemble other tobacco products such as pipes.

Researchers have begun responding to this diversity to categorize the devices. This figure is from work by Rachel Grana and colleagues, and it illustrates some of the major

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device types. Briefly, I want to describe these. So at the top you'll see disposable and rechargeable cigalike devices. These typically closely resemble traditional tobacco cigarettes. Followed by pen-style devices. These typically feature a refillable chamber or clearomizer that can be refilled with custom liquids. And, finally, they describe a tank-style or mod type of device. These are typically larger and feature customizable components for both their look and their function, such as how hot the heating coil might get in the device.

Adding to this complexity, reports suggest that users employ a variety of terms to refer to these devices. This is an illustration from a *New York Times* article that many of you are probably familiar with. And it shows on the upper left a traditional tobacco cigarette along with two examples of cigalike e-cigarette devices. On the right there's a set of devices sold to -- or referred to as e-hookahs. And at the bottom, a pen-style e-cigarette often referred to as a vape pen.

So while we can feel confident that e-cigarette use is increasing, there are still many details that we don't know as much about. Most national as well as smaller-scale studies

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don't currently capture detailed data on e-cigarette use in terms of both the range of devices used or the patterns, such as frequency or concurrent use related to these different devices. Such data are challenging to collect.

As many of the other speakers have noted, new products are constantly being introduced into the market, device types are constantly evolving, and the marketing used to sell these devices is changing. Such marketing could, in turn, influence the terms consumers might use to refer to these devices as well.

Furthermore, e-cigarette use behaviors are challenging to measure, in part because they're not usually captured by measures used for cigarettes, such as cigarettes per day. For example, users might not be able to easily know how much e-liquid they consume, especially in devices that are refillable, like this example of that pen style.

So, in light of these challenges and lack of information, we conducted an exploratory study of e-cig users to inform our ongoing research in the area. And the following results are part of this exploratory work.

So, for this study, we recruited participants by placing ads on craigslist in cities around the U.S. Those who

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responded to the ads were asked to complete a brief screening survey, and a convenience sample of 196 respondents was drawn from those who completed the screening based on the criteria you see here, including having used an e-cigarette within the past 7 days.

So data were collected via web survey in February and March of this year, and our final n was 136. We didn't include 60 cases, including those who weren't eligible based on a confirmation of eligibility criteria, non-response, and incomplete data for key variables of interest, which was use of the e-cigarette devices for all five device types we measured.

So, in the final analytic sample, we had a mean age of 32, close to a 50/50 split in gender, and the state of residence of the respondents reflected our recruitment approach.

So we measured current use for five e-cigarette device types. When asking about each type, we used sets of 2 to 4 sample images. This helped us to ensure that responses weren't solely dependent on our use of particular terms to refer to the device types. For example, we used images of products sold as disposable hookahs, like the one you see here, when asking about use of disposable cigalikes along with several other sample images.

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For each of the five device types listed here, disposable cigalike, rechargeable cigalike, pen style, tank style, and vapor pipe, we asked respondents to report whether they used each every day, some days, or not at all. Using these data, we wanted to describe the users of these e-cigarette devices to help inform some of our subsequent work.

As you can see here, respondents reported use for all five device types, and many reported multiple device types that they used. Just to highlight some of these results, rechargeable cigalikes were the most popular device type used every day at 25%. Disposable cigalikes were the most popular device type used on some days at 51%. And vapor pipes were the least popular device in our sample.

So, in our sample, over 70% of the respondents reported using two or more of the e-cigarette device types on some days or every day. We asked multiple device users which device they used most often to determine their preferred device type. This enabled us to categorize the respondents into exhaustive and mutually exclusive categories based on their preferred device.

Here you can see for each device type we have the percentage who prefer this device because it's the only one they use, and the percentage who prefer this device among

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others they are currently using. In the case of vapor pipes, only one respondent preferred that device type. All other vapor pipe users indicated they preferred a different device type that they currently use. Across the five types, those preferring rechargeable cigalike devices were most often multiple device users at 81%.

Here we see age by preferred device, and those who preferred the cigalike type devices averaged a little bit older than the others. Looking at sex by preferred device, you can see cigalike and pen style devices have slightly more female users, but fairly close to 50/50, while those preferring tank style devices were disproportionately male at 71%.

On this slide you can see some variations in race across the device types for disposable cigalikes and tank style devices. However, these should be interpreted with caution since we collapsed all the minorities into a single non-white category due to small sample size.

Looking at education, we see some differences. You can see larger percentages of those preferring disposable cigalikes and pen style devices are high school or less compared with those for rechargeable cigalike and tank style devices. This made us wonder perhaps this population might be more price

sensitive, which could influence preferences since the rechargeable cigalikes and the tank style mods can be more expensive.

We also asked several questions to try to get a sense of how use patterns and behaviors might differ by device type.

So respondents were asked about the locations where they used their preferred device: inside, outside, or a car, and they were allowed to check all that apply. Those who had used their device within the past 24 hours were asked to report for that period. Those who had not used their device in the last 24 hours were asked to report for the past 7 days. As you can see, a large percentage of tank style users, 94%, reported using the device indoors, and relatively large percentages of pen style and tank users reported using in a car compared to the cigalike users.

We asked respondents who used their preferred device within the past 24 hours on how many occasions did they use the device in that time period. Responses varied widely, so we report the median values here. Pen and tank style users reported more median occasions than cigalike users. However, the ranges were wide, and we did see some evidence that some users were reporting values over 50 and into the hundreds, so

it's not a single outlier in these two cases.

But this made us wonder about whether some users might tend to be episodic, while other users might use their devices more continuously or graze throughout the day, perhaps to maintain a nicotine level, for example. And, finally, the puffs per occasion reported by the users was fairly consistent across the devices, but also had a wide range. So these results are limited by several issues, of course. These data are from a convenience sample, and they may not generalize to all electronic device users, electronic cigarette device users, that is. And then recall of use behaviors may be limited. The number of occasions may be limited in terms of recall, but also the definition of occasions and what users perceive to be an occasion may vary. Similarly, a number of puffs per occasion may be difficult for users to recall.

These results are also descriptive and exploratory, and our dataset includes too few cases to conduct inferential analyses on these types of use patterns. We do think that these results are encouraging in terms of supporting the need for further study on several different issues. Results of further study could inform assessments of toxicant and nicotine exposure due to e-cigarettes, since devices likely have

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different toxicology profiles and use patterns may affect consumption levels.

Such results could also inform regulations and policies related to the impact of e-cigarettes and population health if types of individuals are likely to use different devices varies by demographics or other tobacco use behaviors or if use patterns vary by these characteristics. Lastly, results could inform measures needed to adequately monitor patterns in e-cigarette use, including self-report by others as well. For example, we're working on passive monitoring devices in conjunction with surveys to do this kind of measurement.

So, like all exploratory research, our study generated more questions than answers, and we think it suggests some further examination in several areas. Based on the results, we suspect that e-cigarette users frequently use more than one device type, so that's something to be considered in monitoring going forward. And further examination is warranted to determine whether device preferences may be associated with demographic characteristics, such as age, sex, race, education, and likely others.

Secondly, some devices may be perceived as more acceptable for use indoors, particularly tank or mod style devices that

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don't resemble cigarettes as closely as others, like the cigalike devices. And if there is variation in use patterns across some of these devices.

Thank you.

(Applause.)

DR. DRESLER: Thank you. What an information-packed panel.

Could I please ask the speakers for our panel to come up to the front? We'll get the name tags going. And, again, questions onto the cards, please, and pass them to the people that are passing out the cards, and they will pick them up. We have a half an hour to ask questions, and I can imagine we could go all day, so half an hour for this panel.

So, for our transcriber, the first person on this side is Ms. Ba-bob-ian?

MS. BABAIAAN: Ba-bay-an.

DR. DRESLER: Babaian? Okay. And then Dr. Sarin, Dr. Lee, Dr. McMillen, Dr. Pearson, Dr. Pepper, and Dr. Shiffman. Okay. All right.

Okay. And so as the questions are coming in -- let's see, I had some, but let's start off with this one and -- because we heard about many online studies, okay? So much of the

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information that we have is from online studies.

To what extent are these data representative of the population as a whole? Okay, so we've been hearing a lot about online studies. How representative of what's going on, what are the strengths and weaknesses?

And actually I'm going to stop -- did I hear -- before we do that, I'm sorry. Before we do that -- thank you. There's two new people that didn't give a presentation and with their disclosure, so if you could please state your name, where you're from, and disclosures, please. And then same thing, Dr. McMillen.

MS. BABAIAN: My name is Spike Babaian. I own Vape New York. It's an electronic cigarette company in New York City. I started National Vapers Club in 2009, which is one of the largest e-cigarette user groups. And I sell electronic cigarettes and I profit off of it, so I'm the devil.

(Laughter.)

DR. McMILLEN: I'm Robert McMillen. I'm at Mississippi State University, and I have no conflicts of interest to disclose other than my research is funded by Legacy, by the Academy of Pediatrics, by the Flight Attendant Medical Research Institute, and the Mississippi State Department of Health.

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DR. DRESLER: Thank you.

Okay. So let's go back to that question. Online studies, what are its strengths, weaknesses, limitations?

Dr. Shiffman.

DR. SHIFFMAN: It's not perfect. And the big issue is that not everyone's online, and not everyone volunteers for these panels. I think it was Dr. King who mentioned earlier that, in fact, despite that limitation, when you look -- this is not specific to the tobacco area, but when you look across a lot of areas, the results from online panels tend to do pretty well at mirroring the results of other results like random digit dialing.

And then there is, within the online panel world, there are some panels -- I think someone had already presented and mentioned this -- where they recruit people based on address lists, and if you don't have a computer or access to the Internet, they'll give you one, so it's online data collection, but they don't depend on there being an online panel.

The other thing that's important, it's not a complete solution, is appropriate weighting of the data. And while you might think that with an online panel you're going to over-recruit young people, actually what happens is you over-recruit

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older people, which is also true in random digit dialing because they're the ones hanging around with nothing else to do.

DR. DRESLER: All right.

DR. SHIFFMAN: I say that as a certified older person.

DR. DRESLER: Yeah, but your hair is whiter than mine.

(Laughter.)

DR. DRESLER: Dr. McMillen, did you want to --

DR. McMILLEN: I mirror a lot of those comments. We've done some work with the GfK KnowledgePanel and our Social Climate Survey. It's an annual cross-sectional survey about tobacco control. And a couple of years ago we published a study in *Tobacco Control* showing that our estimates for current smoking using the KnowledgePanel actually were right on top of the estimates for the same period from the BRFSS and from the National Health Interview Survey and from the NHANES. So some very large household surveys, as well as a large telephone survey, and our estimates were right on top. And they were the same for most demographic groups as well. So we've had some good success using online panels.

DR. DRESLER: Okay. Question. So we are -- oh. Go ahead, Dr. Sarin.

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DR. KRISHNAN-SARIN: I just want to add -- I don't do work with online panels, but I do know of someone who wanted to, and my understanding is that recently the KnowledgePanel has stopped, has said that they will no longer ask questions about tobacco products and other substances from minors, so I think it's going to significantly influence our ability to do any of this work using online panels from now on, if that stays.

DR. DRESLER: And actually had a question for you also. What is the law in Connecticut? So you were doing your surveys in Connecticut. What is the law for youth sales and for smoking indoors in Connecticut?

DR. KRISHNAN-SARIN: So the data that I presented were obtained before the law went into place, which basically prevented sale or administration of e-cigarettes to minors. That went into place sometime, I believe it was earlier this year, in the beginning of this year. And -- in March? Yes, okay. And there is also a law that's being considered right now to include e-cigarettes in the tobacco-free law component, but that's not passed as yet. But --

DR. DRESLER: Okay.

DR. KRISHNAN-SARIN: -- you cannot sell to minors now, but not when we got the data.

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DR. DRESLER: Okay. And that is changing across the country, so I always look at that. So anyone else about the online panels?

(No response.)

DR. DRESLER: Dr. Lee, why are more males using tanks?

DR. LEE: You know, I don't really know. We didn't ask about questions related -- like, open-ended kinds of questions that might get at some of that. I wonder if a part of it has to do with the fact that they are, like, kind of larger and more substantial, and they're more customizable, which may be more appealing. But I'm not exactly sure if there's a good answer to your question, certainly not from these data. I think it's a part of the detailed information that really piqued our interest here that we just don't know much about but are planning on following up to try to uncover those questions.

DR. DRESLER: Ms. Babaian.

MS. BABAIAN: The majority of female users report not wanting to use large devices mostly because of the size, also because of the weight. There's not typically somewhere to put it, and male users generally have bigger pockets. Women wear dresses, they have to put it in their purse, they want it to fit, and they feel unfeminine using a large product oftentimes.

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DR. DRESLER: Okay.

DR. PEARSON: And I should say I have an R21 that's in the field that's funded by FDA. We're calling it the MOMENT study, and it has three streams of data. It has qualitative, ecological momentary assessment, and geo-tracking. So I'm familiar with some of the in-process qualitative interviews from about 50 people right now, and what we're hearing from the men is they're getting cigalikes, and they feel like they're toys. And, in fact, there's one -- a quote from one user that I love, he calls it his stupid rut. So it's just not a manly -- a cigalike is not for men. The women, however, no comment.

DR. DRESLER: Okay.

Dr. Shiffman, in your study you had looked at non -- people who -- kids who didn't smoke. Why didn't you assess teens who smoke cigarettes or use e-cigarettes for their flavor preferences and then compare that to adults?

DR. SHIFFMAN: That's absolutely a study that should be done; I'm surprised no one has done it since. But as I said, we set out to do this for a study, and we were most interested in these two groups that had very different dynamics in terms of population impact, so that was our focus. Part of my plea at the end for research is people have asked that question,

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it's a perfectly legitimate question, and the answer is someone should do that study.

DR. DRESLER: Okay. And the follow-up on that: The scale is 1 to 10 on your graph. Isn't 1 and 2 of very little interest?

DR. SHIFFMAN: Yeah, I would say, again, interest. So, to put that in perspective, and that's again where the water and ice cream ratings helped us, is you could get up into the 5 and 6 range. Remember, teens' average was about 0.5, so pretty strong disinterest. But even among the adult smokers, the ones who hadn't already adopted e-cigarettes, the interest is pretty modest. It was significantly higher, but it didn't blow the top off the scale, I agree with that.

DR. DRESLER: Okay, all right. Dr. Shiffman, this one's for you, too.

DR. SHIFFMAN: I'm going to be busy.

DR. DRESLER: Please comment on youth sample and how non-tobacco users -- flavor preference in youth population, in general. So I think that follows up on -- so represent flavor preference in youth population, in general. So do -- you're asking me to interpret what the person was asking, okay. So --

DR. SHIFFMAN: So short answer is I think what I will do

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is stick to the data that I'm aware of, which is we have the data on the non-smoking teens. What the flavor interest would be of the smoking teens, I don't know.

DR. DRESLER: Okay. So here's -- it kind of follows up on that, sort of: How do we discourage youth, especially the ones who have never smoked, from using e-cigarettes while making e-cigarettes an appealing alternative for adult smokers?

Okay, I think that's a million dollar question. So shall we start -- do you want to start? Let's go across on the million dollar question.

MS. BABAIAN: What we found recently, in the last year, is that we've changed our packaging on our products, and it's not necessarily about the flavor; it's about how you market the flavors. We've eliminated the names of the flavors. We don't call it bubble gum; we don't call it, you know, berry tree or gummy bear. We have three-letter codes for all of the flavorings, and I think that by changing the packaging to solid black packaging with minimal color and simple names that do not denote flavors, it -- not eliminates, but it reduces the urge of children to be attracted to the visual of the product. I don't think it's about limiting the flavors; it's about changing the image of what the product looks like, and I think

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that FDA should focus on how they regulate packaging the products and appeal to youth.

DR. KRISHNAN-SARIN: I'm really glad to hear you did that. I think that's a great step in terms of reducing appeal of the flavor of the products to teens. As I said in my talk, I think there are multiple ways you can approach this. One is flavor. The other is really trying to figure out what appeals, what else appeals, to the kids. And as I said, a big one that we are discovering now is smoke tricks, so that's something else that needs to be taken into consideration also.

And then, you know, putting laws into place and really monitoring them from the perspective of making sure that sale to minors doesn't happen. Even though we have this law in place in Connecticut, teens still manage to get their hands on e-cigarettes and use them, so how is that happening? You know, we did a really phenomenal job over the past few years of making sure that we prevented access to cigarettes, and we had great laws in place and methods in place. I think we can learn from those and really put them into place the same way for e-cigarettes.

DR. LEE: Well, I mean, I think we saw a little bit of an age difference that I wasn't too surprised by in our data where

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the devices that were cigalike tended to be a little bit older, and we looked at adults and not youth. But I would suspect that the devices that more closely resemble a cigarette would probably be less appealing to youth, in part because of what we're hearing anecdotally about the tricks and the flavors, but also I think the novelty of the device. It's a lot more novel to have a device that looks a lot different, that operates a bit differently, that's more customizable than something like a cigarette.

DR. KRISHNAN-SARIN: I just want to mention that yes, indeed, we are finding that teens like the tank devices and the rechargeable tank devices the most. That's what's most popular.

DR. McMILLEN: I think it's a really good question because we really do have to balance the potential for public health benefit among smokers with the concerns about nonsmokers using these products when they're made appealing. Our Social Climate Survey of tobacco control found that this year 18.9% of past 30-day e-cigarette users are never smokers. This is adult population. And that, obviously, is not a public health benefit. And we also, like your study has found that -- we asked about product preferences, and nonsmokers tended to

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prefer the tank type -- well, the e-juice products and the non-cigalike. So I think that one of the challenges is how do you make a product that's appealing to smokers who want to quit and not appealing to nonsmokers, especially younger adults and adolescents.

DR. DRESLER: Before we go on, clarify that for me. So you had said in your survey that the adults who are using the electronic cigarettes prefer -- 18.9% wanted the tank system.

DR. McMILLEN: No, I'm sorry; 18.9% of current electronic cigarette users are never smokers, so they're never smokers, and the majority of the never smokers who use the electronic products prefer, I think it was like 77% prefer the e-juice types, and they also prefer the non-cigalike products.

DR. DRESLER: Which is the same one you said the youth want? Okay. I just -- okay.

DR. PEARSON: I also think it's important to keep in mind that if we're talking about smokers, the relative appeal of e-cigarettes compared to cigarettes is important, so we need to do things like eliminate menthol in cigarettes, make cigarettes harder to get a hold of, and make them less appealing for adults and youth.

DR. PEPPER: I'll start by saying I'm not an expert on

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youth and e-cigarettes, so take that as a caveat here. A couple of things also occurred to me, listening to what people have said. I think putting some restrictions on advertising could potentially reduce youth appeal. We have some good evidence from years and years of cigarette marketing about exactly what features of ads appeal to kids.

I would say the other thing that comes to mind is there's been some research by some colleagues of mine at UNC about how incredibly easy it is for adolescents to buy e-cigarettes online. So they had a bunch of adolescents actually try and buy e-cigarettes online, and the vast majority of them were successful. So I think if we really want to make sure that we're blocking youth access to the products, that ensuring that that's not happening is really important.

DR. SHIFFMAN: Just to reinforce two points that have already been made, I mean part of the equation is the appeal of the products, but the other part of the equation, which is why we're here today, is regulatory constraints on both, things that make the product appealing like advertising but also access. And as people have said, this is a problem we faced with cigarettes. I wouldn't say we've completely solved it, but we've made a lot of progress. We need to apply those

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learnings.

And the other issue that Jennifer brought up is very important, which is for the adults. It really is the relative appeal of e-cigarettes relative to the combusted cigarettes that are killing them, and so the more we do to make combusted cigarettes difficult to get, expensive to get, the more we emphasize the information about the relative risk, which right now we're actually confusing people.

That's a way to have a specific appeal to people who are -- adults who are currently smoking that doesn't really get into youth appeal. In fact, the more you frame this as a harm reduction product, probably the less appealing it would be to kids, because kids want to see it as fun, I can do smoke tricks. If we did a better job than we currently do, emphasizing it as a harm reduction tool, I think that would be differential appeal to adult smokers.

DR. DRESLER: Okay.

Dr. Pepper, do you -- a question for you. Do you have any data on reasons for starting and continuing to use e-cigarettes differs across the categories, cigarette-like or tank?

DR. PEPPER: Unfortunately, we do not have that data, although Dr. Sherry Emery at University of Illinois at Chicago

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is doing a follow-up study to the one that I presented data from, and I believe that she is going more in depth about differences and product type. I think that's a super important area. And just a really huge caveat to a lot of the research we've seen presented today, my own especially.

DR. DRESLER: Okay.

And then Dr. Lee. Your question on use indoors, do you differentiate that from home, workplace, public place? So when they're using it indoor, where are they using it indoors?

DR. LEE: I don't have the exact verbatim of the item in front of me, but we do indicate that it is indoor areas, and then we give a couple examples, such as the workplace or home. And then outside, outside of a building. And in a car is more straightforward.

DR. DRESLER: Okay.

Dr. Krishnan-Sarin, you mentioned that most youths obtain the e-cigarettes from someone else, and you stated this could be family or parents, and we heard in the previous session some data on that. Could you talk about this further and any studies that show how often parents purchase these for their kids? And do you have evidence, too, from the morning session that said, you know, Dr. Abrams had said that parents who

smoke, their kids are more likely to smoke. Do we have any differentiation between parents using e-cigarettes?

DR. KRISHNAN-SARIN: So, you know, this is -- I always find that every version of our survey, we learn from the first one, and then we insert questions in the second one, and you say why didn't I ask that the first time.

And this is one of those things that we did not ask in great detail in our first two surveys, but in our current survey that's ongoing, which is the largest one yet, we have questions about parental use, about getting e-cigarettes from parents, getting e-cigarettes from their peers, so we'll be able to answer a lot of that. I don't have the answer right now. But my general perception would be that many kids do tell us that they get their e-cigarettes from their parents or their parents buy it for them because the general perception is that it's a safer product. And also many times the kids also -- someone presented some of our data earlier today -- they also start the product without nicotine in some cases, so -- and then they move on to using the product with nicotine, so we have to, you know, basically dissect that. We haven't done that yet.

MS. BABAIAN: I just wanted to mention that you also noted

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that most children are using fruit flavors, but if they're getting them from their parents, then maybe it's really their parents that are using the fruit flavors.

DR. KRISHNAN-SARIN: Very true. So we have to do that to see whether everything is coming from their parents or if something is coming from their peers. You know, the peers might be older peers might be using it, also. And, you know, another area which is completely unregulated and -- that we are starting to do some more research on is vape shops. You know, vape shops have rules and regulations, but they are many times very open in terms of who they let in. Not all of them, but some of them.

DR. DRESLER: Anyone else want to -- so this is a question for you and Ms. Babaian. I'm sorry, Babaian. I'm trying -- okay. There was a lot of discussion of flavors, but it is my understanding that experienced users customize their flavors. Could you comment on the popularity of customizing flavors and if it plays a role in people initiating with e-cigarettes or with them in persisting?

MS. BABAIAN: I would say that the majority of people will choose a flavor, the majority of new users will choose tobacco or menthol. It seems to be 1 to 5 weeks before they convert to

a flavor that is not tobacco or menthol in the majority of the cases. Once they convert to flavors, they often will experiment with flavors mostly because when they're using open tank systems and they have a little bit left of one flavor and they only have a different flavor left, they'll put it in and then they'll end up with a mixture, which then makes them want to try different flavors and mixing flavors and oh, look, this might taste good with this.

It also maintains their interest. People seem to get bored of flavors; they labeled it vaper's tongue, where a flavor -- you become numb to a flavor. If you were to eat ice cream every day, you would eventually get sick of the same flavor and want something different. So people do seem to change. They don't seem to change cigarette brands when they smoke cigarettes, but with e-liquid it does seem that they -- the majority of them do change occasionally, more so than with cigarettes. However, there is probably 40 to 50% who find one flavor and stay with that same flavor for many years.

And I've been doing this 6 years, and we've seen people who do the same flavor for 3 or 4 years straight, and you have a record, you know, in your point of sale of the history of what they've purchased, and it seems to be the same flavors

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over and over. Occasionally a new flavor will come, they'll buy one bottle of it, and then go back to the same flavor.

Mixing in the store is something that we don't particularly see because we only sell sealed bottles that came from a lab. We don't allow open bottles or mixing in the stores, but there are vape shops that have flavors there, and they mix them up right in front of you, and it's unsanitary and not a great idea.

(Laughter.)

DR. KRISHNAN-SARIN: So I just want to add that the slide I did not show you that I left out by mistake had three items on it. The question was what is cool about e-cigarettes, and we asked the kids this. The three things were the presence of flavors, smoke tricks, and the ability to customize flavors. So customization of flavors is very popular amongst the kids and they -- you know, it goes with the whole risk-taking, sensation-seeking personality. They want to try new things.

UNIDENTIFIED SPEAKER: Vapor tricks.

DR. KRISHNAN-SARIN: Vapor tricks, too. Yes.

DR. DRESLER: Okay. Anyone else?

(No response.)

DR. DRESLER: Okay. If you go into a Vapefest of

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committed vapor quitters, you never see a cigalike in spite of all the point of sale advertising for MarkTen and alike.

Recent cigalike sales are down while a decline in cigarette sales have declined. What does this tell us? So there's a lot of advertising for MarkTen and alike, the cigalikes, but recent cigalike sales are down and the decline in sales are down. What does that tell us?

MS. BABAIAN: It tells us that cigalikes don't work. You can advertise them as much as you want. If the product does not help you to achieve your goal, which we saw that most people's goal was to reduce or eliminate cigarette smoking, people are not going to continue to buy the product. The biggest advertiser for electronic cigarettes is word of mouth. Ninety-nine percent of e-cigarette stores don't ever advertise. Vape shops, I'm sorry. Vape shops do not advertise, ever. Their customers tell other customers, they see that they don't smoke anymore, and they say where did you get that and why don't you smoke anymore? That's -- we made t-shirts in 2011 that said if it looks like a cigarette, you're doing it wrong, because they just don't work.

DR. DRESLER: Okay.

Dr. Shiffman.

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DR. SHIFFMAN: No data, but just an opinion. I think part of what's happening, we've had several references to the fact that the products are evolving quickly, and one of the ways they're evolving is people are -- makers of these products are figuring out how to actually deliver nicotine, and Tom Eissenberg's data and others suggest that the early cigalike products, not as a function of them being cigalikes or not, just weren't very good at that. So I'm not sure that this categorization is going to serve us that well going forward because the -- at this stage, the evolution is that the early cigalikes were not very effective. The early tank products are more effective, so it may not be the form but the effectiveness of nicotine delivery. And I suspect that we're going to see some, as this matures, some sorting out into different market segments because a lot of the tank products are people who want to make this a hobby, right?

In other words, it's not a pick it up and use it; it's oh, buy liquids, mix it, maintain the tanks. I think that's not going to be a huge percentage, and it may well be that if cigalikes get better at delivering nicotine, that the market comes back that way. So I just think this market is evolving so quickly, we need to be careful about drawing any lasting

conclusions.

DR. DRESLER: Plus there's gender difference that we've heard about.

DR. SHIFFMAN: Yeah. And I think that has to do with that, how much does someone want to fiddle with a thing versus just have a product they use.

DR. DRESLER: Dr. Sarin.

DR. KRISHNAN-SARIN: As far as the teens are concerned, they don't like the cigalikes very much because it doesn't allow them -- it's not a manipulative product, you know, they can't play with them, they can't put different flavors in it, and that's what makes it something that's not that attractive to them. So that's something to keep in mind when you're looking at different products, too. They love the tanks just because they can play around with it.

DR. DRESLER: Let me come back to something, too, because I just mentioned the gender differences. In youth, are you seeing the gender difference, too, between the cigalikes and the tanks?

DR. KRISHNAN-SARIN: We have looked at specifically cigalikes versus tanks. I don't think we have -- we have the data, but we never thought of looking at it. But as far as

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flavors, we're not seeing any gender differences in youth.

DR. DRESLER: Okay.

MS. BABAIAN: The cigalike products, the battery is small in size physically, which doesn't allow for a lot of battery cells. When a smoker -- and as someone noted, the majority of e-cigarette users that are using this product solely were heavy smokers. When you have a battery that only will allow for 2 hours of use and the cigarette smoker was smoking all day cigarettes, the e-cigarette needs to last all day. So unless they have 10 batteries to last them all day, the product does not work. If there were a way to harness -- technology will not allow for us to harness a full day worth of battery power in the size of a cigarette. We don't have the technology to that in that size cell yet. That's why they're less -- part of why they're less effective at delivering, because they don't last long enough.

DR. DRESLER: I just wonder if Tesla is getting into batteries for cigarettes.

(Off microphone comment.)

DR. DRESLER: Nuclear power. Oh, okay. I think that's a whole different regulatory --

DR. SHIFFMAN: We might need a hack with a solar cell.

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DR. DRESLER: Solar. Okay, all right.

What role does the pharmacologic effects of nicotine have on the reasons for use? So can the panel comment on youth use when used alone or socially? So try that.

DR. KRISHNAN-SARIN: It's a great question. I don't have a direct answer for you. The way we have addressed it so far is through surveys where we are actually -- where we ask kids, you know, what I said earlier, did you start with nicotine? Are you using nicotine right now? And we have a lot of questions that we ask about, you know, whether they're using it for smoking cessation, whether it alleviates nicotine withdrawal, those kinds of questions. So we are looking at those right now, but that would be only relevant for smokers. You know, for the nonsmokers, we are just monitoring how they use the product.

However, other work going on in the Yale TCORS, the tobacco centers, is actually looking at administration of these products in a very well controlled fashion, controlling pharmacology, controlling nicotine, controlling the flavor, and administering it both to young adults as well as older adults to actually differentiate whether the pharmacological effect of nicotine versus the potential pharmacological effect of

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flavors, too. So we hope to have those results soon, but we don't have the answers yet.

DR. DRESLER: Okay.

Dr. Pepper.

DR. PEPPER: Quick comment about adults. You know, one of the things I mentioned is that one of the reasons people give for stopping use is inefficient nicotine delivery, that they're not getting a relief of their cravings. I think as the market changes and the products become better, we're going to hear that less and less as a reason that people stop using.

DR. DRESLER: Okay.

MS. BABAIAN: We had a teen come into our store. It's 21 and over in New York City now, and we had a teen come into our store from Sweden who told me that he needed an electronic cigarette, and I said well, I can't sell you anything; you're not 21. He showed me his passport, and he said my doctor recommended it. And I said your doctor's not in America, is he? And he said no. He said but -- he suggested that the benefit would outweigh the risk because I have, you know, bipolar disorder and manic depression and I'm suicidal.

And I said I'd love to help you, I'm really sorry, but I'm not able to sell you anything, and he said okay, I'll have to

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go buy some gum. And I said I hope that you're still allowed to do that in New York, I don't know. But the point is that the benefits of the nicotine have to outweigh the risk. Every day people look at a pack of cigarettes, and it says this will probably kill you, and they continue to smoke them. There has to be some benefit to the user. You would not offer an apple to somebody and say there's a 50/50 chance this is going to kill you and someone would eat the apple anyway. Everybody would say no. There has to be some benefit to the user.

Now, obviously with youth, they're developing, their brains are developing, it's a different situation, and it's better to prolong away from nicotine as long as possible. And I'm glad that New York made it 21 and over, because if they had, maybe I wouldn't have started smoking at 15. But there has to be some benefit, and if the benefit outweighs the risk in that situation, it may be necessary.

DR. DRESLER: Okay.

Dr. Shiffman.

DR. SHIFFMAN: I guess just a broader comment, and this is certainly not about youth or initiation, but when we say about adult users that they're smoking to get the nicotine, it's absolutely true, but it's also an oversimplification. There's

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a lot of evidence both from human studies but also a lot of animal studies that a lot of the cues, including sensory cues like flavor, like the sensory effects in the throat, the manual manipulation of the product come to be conditioned, reinforces to an extent that they really become part of the behavior that's ingrained, and that explains, in a way, why there's product use even among the products that don't do such a great job of delivering nicotine.

So I think just as we think about that, we should think about it in terms of behavioral pharmacology and not oversimplified, you know, what's it doing at the receptor, because it's also subject to a learning and conditioning process. And let's remember that the typical smoker has had tens of thousands or hundreds of thousands of associations between those cues and behaviors and the nicotine hit, so those aspects play a huge role.

DR. DRESLER: Okay. So I know that that red light is blinking, but I have one more, okay? And you get an hour for lunch, so -- okay.

So the next one is looking at flavor preferences. Has there been a consideration between the smell versus the taste? And I'm looking at how that can have behavioral implications

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for that, so Dr. Shiffman, and then we'll --

DR. SHIFFMAN: Well, basically it turns out most of taste is smell. Most of our sensation of taste comes from the smell. This sounds bizarre, but you can do a demonstration that if you block someone's nose, you can convince them that the apple they're -- that you tell them they're biting into an apple and it's an onion, and they can't tell. So there's actually very little -- 80% of taste is smell.

DR. DRESLER: Okay. Anyone else?

MS. BABAIAN: I think that people do sometimes smell the flavors before they taste them, but it's more association of their mind. Every day we have hookah users come into the store: I do apple hookah, I do this. And notice I use the word "do" because when you ask them if they smoke, they say no, I do hookah. They're not aware that hookah is tobacco, so when you are all doing your studies and you're saying they're never smokers, that's not true. They may be never cigarette smokers, but they are smoking; they just don't consider hookah smoking.

So it's very important when you research to phrase your question, do you do hookah or do you use hookah, because they don't understand that there's tobacco in it. The flavors are what makes hookah enticing, and so we have hookah users

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frequently come in who say I only do hookah once a month, and we say to them, if they're over 21, you should not use nicotine because you're not getting enough nicotine in a month to warrant needing the nicotine. They say but I like the way it makes me feel. I said but you're doing it for the flavor, for the taste. They said yes. And I said well, then you don't need nicotine. So it's important to understand, for them, that while the flavor is important to them, the nicotine isn't necessarily. They're doing it for the enjoyment and the experience. It's social.

DR. DRESLER: Okay. All right.

And so with that, thank you very much, panel. Speakers and for the presenters, thank you.

(Applause.)

DR. DRESLER: So lunch, we have 1 hour, 12:15. 1:15 to start back up again. There is the restaurant that's outside, as you heard previously, if you would like, for that, but we'll see you back here at 1:15.

(Whereupon, at 12:15 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(1:17 p.m.)

DR. DRESLER: Okay. All right, so we're going to get started again. Thank you very much. For those of you who are back, and as I just said, please, I will apologize that some of the people are still getting served in the restaurant, so they'll be coming in. And hopefully quietly for us.

So our next session is going to be on marketing, and our first speaker is Dr. Rachel Grana from the NCI speaking on Smoking Revolution? A Study of Retail Website E-cigarette Marketing.

DR. GRANA: Thank you again for this opportunity to speak with everybody today. I welcome you back from lunch. I will try to keep everybody awake. I have pictures, try not to do too much text-heavy, so hopefully we'll enjoy the rest of the afternoon.

I think that the marketing of e-cigarettes is one of the key important points in considering the total population health effects of these products. I do not have any financial disclosures. I do show images and advertisements, and these are strictly for educational and exemplary purposes only. And I want to note that the original research that I'm presenting

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in this talk is already a published paper that I did at -- while I was at UCSF.

And the examples and information and views and interpretations are mine and do not reflect official views of any government agency. I also want to acknowledge the collaborators from UCSF that helped me conduct this work. I'm very indebted to them.

So I think that we can all see how relevant that this topic is in that Oxford English Dictionary picked, for their word of the year, the word "vape" or to use an e-cigarette. And it seems, looking at the other words that vape beat out, like clickbait and normcore, that they're trying to pick culturally relevant terms. And so I think one of the ways that things get conveyed as culturally relevant or socially interesting is also by how the products are used in the population and also the marketing as well.

Sorry, this is advancing a little bit on its own.

Although my study focused on evaluating the messages in web-based marketing, an important point of context that has emerged, particularly over the past few years since I conducted that study, is widespread distribution of the products in the convenience store environment and in vape shops, which are

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specialty shops dedicated to selling e-cigarettes and other electronic nicotine delivery devices. These are often social venues, and as was already mentioned in a previous panel, there are e-liquids that are customized there, and sometimes, like I said, they're social environments.

Also a recent phenomenon the past few years since we were looking at the online-based marketing, which is primarily how the products are being sold, is they're being advertised on television in very expensive campaigns. This was already alluded to in the first talk of today. And a nice study by colleagues at RTI show that the exposure to this television marketing for e-cigarettes is reaching a youth and young adult audience as well as adult audience.

And this is also the promotion -- the marketing is also in the context, as has been already noted very well today, as an increase in youth e-cigarette use. That's the third bar over from -- third group of bars over from the left. These are data from the NYTS showing a really extreme, you know, increase in e-cigarette use among teens and also a decline in some other tobacco products and an increase in some other use of tobacco products like hookah. And, overall, the total tobacco product use has actually remained the same over the 4 years, not

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statistically significantly different. So this is an important point, that the products are also used together in conjunction with other tobacco products and in the context of multiple tobacco product use, and that's not declining, which I think really highlights the importance of valuing the marketing in the context of FDA's public health standard, which is to evaluate the impact on all segments of the population, of all the components that are under regulatory authority, one of which being the marketing of the products.

And so we look at the impact of the marketing on nonsmokers, particularly youth, but also in the context of this other tobacco product use, and how does the marketing perhaps influence the uptake or discourage the uptake of other tobacco products.

So that just hopefully sets the stage a little bit, and now I'm going to focus on the findings from the study I conducted in 2012 that was published in 2014. And what we did is we wanted to see what are the main messages that consumers are exposed to on the web from retail e-cigarette websites. So we did a series of searches using various search terms on two search engines. We narrowed down the hits we got to 59 sites that met our inclusion criteria, which is that they had to sell

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primarily -- well, only e-cigarettes and e-cigarette-like products. No things for marijuana or marijuana vaporizers; I just want to say that specifically. They had to be for a single brand and not just be a portal to sell several products, and in the English language.

We created a coding guide, which just means that we wanted to determine ahead of time what are the definitions of the themes and the messages that we're trying to capture and agree on them because four of us coded these websites. Then we went through a process to establish reliability among the four of us to code them.

And I'll just give you some selected findings of what we found. One of the main messages conveyed that using e-cigarettes was healthier than cigarette smoking. Here is an example of one of the sites. This was present on 95% of the sites. And the health-related messaging usually contrasted the risks of tobacco products to those of e-cigarettes or usually conveying that there was an absence of those risks, such as there's no tar or carbon monoxide. One of the most overt examples, of course, of health-related messaging was present on about almost a quarter of the sites, and that's through the use of physicians and physician testimonial or endorsement. If you

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recall that in the past, the tobacco industry, you know, back in the '40s would advertise cigarettes as being endorsed by some doctors. So this is a reprisal.

And another popular theme was that you could avoid the risks of secondhand smoke or that they wouldn't be putting others at risk by exposure to secondhand smoke. This is an exemplary quote from one of the sites: "Electronic cigarettes do not produce harmful smoke...including tar and carbon monoxide...only water vapor" vanishing "in a few seconds leaving behind no toxic secondhand smoke."

But sometimes this messaging was a bit dual in that they'd also emphasize that it would look a lot like smoke, it would be as thick as smoke, but don't worry, it wasn't smoke. So you can see they're trying to actually emphasize some similarities with cigarette products. And then another popular theme was around smoking cessation. Sometimes this was overt, sometimes it was through testimonial, and sometimes they would just be sort of bringing up the topic. And this is one of the examples of one of the more overt ones, so you can see it says quitting smoking "With Altimoff E Cigarette, quitting smoking is easier and less stressful."

Another example is that sometimes it would just emphasize

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switching to the e-cigarette product, but sort of this message seems to be designed to appeal to the smoker who's considering quitting but maybe isn't quite ready and so allaying maybe some of the hesitance, just saying you can switch to the product.

Another popular theme was emphasizing the benefits of using the product anywhere. This was present at 88% of the sites and usually explicitly stated some venues in which tobacco smoking would be restricted and that they wanted to convey that the e-cigarette could be used.

And some -- on 71% of the sites, we found messaging that actually went more explicitly, instructing potential users to circumvent smoke-free laws using their products, such as "Beat the smoking ban" or "Experience the freedom." And this is a particularly concerning message as smoke-free laws have the benefit of, of course, protecting bystanders from secondhand smoke or exposure to certain pollutants, but also they support quitting and they encourage a social norm, that is, to smoke-free and nonsmoking and so encourage you to not smoke.

And then the fourth message I'll focus on is lifestyle benefits. So we coded for themes that conveyed lifestyle benefit or, for instance, messages or images that conveyed that you would have an increased social status or that you would be

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somehow cooler, more exciting, or more glamorous if you use the products.

You can see that this e-cigarette, for instance, is called Vapor Couture, which couture, you know, is fine clothing. And then there's also -- there were themes around socializing and that your friends will thank you for using an e-cigarette or showing videos and images where people are socializing. And then romantic involvement as well.

And there's a presence of celebrities on these websites. You probably are already familiar, back when I was doing this a few years ago, this was sort of new, but probably you've seen these television commercials with Jenny McCarthy advertising the blu e-cigarette. These kind of images or references to celebrities were on about a quarter of the websites. And, again, the tobacco industry has used, in the past, use of celebrities to convey a positive social norm around using cigarettes, so this is a bit of reprisal of that.

And then we documented that there was an encouragement on the websites to go to the brand or the company's social networking sites, which is another venue to perhaps promote the products or just interact and engage more directly with a potential consumer. And I think this is also an important

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finding in that this is a less-easy to monitor environment and presents some challenges, especially in restricting to youth or, you know, young people for seeing some of the messages and interacting with the brands on these social media, as well as youth and young adults are, you know, heavy users of these venues.

So some other findings. You know, we did a few other things in the study and one of the things we did is we documented the presence of the flavors in which the products were available. So several flavors were offered for these products. In descending order in the table, you'll see that the predominant flavors offered were tobacco, mint, menthol, fruit, and candy flavors, and to a lesser extent, there were these novelty flavors that have been, you know, widely talked about already, like gummy bear or Belgian waffle.

And we also looked at -- this is a little different kind of finding, not exactly marketing, but I think it's interesting. We also documented how they advertised the strength descriptors for the nicotine content that might be in the product, and often these were similar to tobacco cigarette strength descriptors like full-flavored, mild, ultra-light, light.

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But what's also important to note here, on your right, is that when there was a strength descriptor given and a nicotine content that was corresponding to it, across the sites they didn't mean the same thing. So, for instance, if you look at the ultra-light category, it could represent 6 mg of nicotine or 11 mg of nicotine. There was really little standardization that we found, and I thought that was interesting and important for consumers' interpretation of what they're getting.

So just to wrap this up a little bit, you know, what did we take away from our findings? Well, one thing that was pretty impressed upon us that in the past few years has been noted is that -- and was noted today -- is that e-cigarette marketing and promotion really is reminiscent of a lot of the tobacco industry marketing and promotion, particularly the use of doctors' endorsements way in the past, but celebrities' continued use of -- you know, celebrities or other youth appeals, lifestyle benefit, glamorization, and rebelliousness, freedom messaging.

And what's really concerning about this is it might have the same effect, and in fact, we're seeing increased youth uptake of these products. So nicotine, you know, is an addictive drug. We've heard a little bit about that today,

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too. And these products are being promoted in a similar way. So the concern is that it might have a similar effect.

And, particularly, I wanted to just address the flavors, as that was a lot of what we found promoted on the sites. And we know that flavored tobacco products, at least, have been used to recruit youth and have -- or have disproportionate appeal to youth and masks the harshness of smoking, so the flavored products are of concern to public health.

So just to wrap up a little bit. Marketing is similar to tobacco product marketing. It includes these unsubstantiated health and cessation messages. And we've heard a bit about the debate about cessation and what you can glean from the data and how you can interpret them, but I think we would agree that, based on what the evidence is out there right now, we don't have a clear picture of cessation benefit of these products. There's really a lot of mixed evidence.

So I think the overt advertising is not really based in fact right now. And also the health effects are still really emerging for these products. At the other two previous public workshops, we saw a lot of new data coming out to rapidly try and characterize what could be the health risks, so some of this, absolutely no carcinogens or no tar might not be exactly

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true.

And the marketing particularly promoting to youth and young adults and suggesting to use these products to circumvent smoke-free laws is particularly of concern for population health effect, as that might be where you have a lot of interference with a potential benefit of these products, if you have interference with an existing tobacco control strategy like smoke-free policies that are very effective. Undermining that might have deleterious public health effects.

So thank you very much.

(Applause.)

DR. DRESLER: Okay, our next speaker is Dr. Pallav Pokhrel, and he will be speaking on Effects of E-cigarette Advertising on Explicit and Implicit Attitudes among Young Adults.

DR. POKHREL: Thank you. Hi. My name is Pallav Pokhrel, and I'm from the University of Hawaii Cancer Center, so most of the research that I'm going to present today has been funded by Tobacco Regulatory Science Program. And some of the data that I'm presenting today has not been published before.

So my lab currently conducted studies on the effects of e-cigarette advertising on young adults. And some of the --

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today, the study that I'm going to present today, the first one is a cross-sectional study, and the second one is an experimental study, so I'll briefly mention the cross-sectional study, which has been published before, and then I'll talk about the experimental study which has not been published before. And I'll briefly discuss the conclusions of the studies.

So the cross-sectional study was conducted to test the hypothesis that higher receptivity to e-cigarette marketing is associated with higher recent e-cigarette use among young adults via increased perceptions that e-cigs are less harmful than cigarettes. As we have heard from previous presenters, e-cig marketing is widely prevalent, and one of the main reasons why individuals use e-cigs is the perception that e-cigs are less harmful than cigarettes. And young adults, of course -- so the highest prevalence of e-cig use.

So we wanted to test whether higher receptivity to e-cigarette marketing is associated with higher recent e-cigarette use via increased perceptions that e-cigs are less harmful than cigarettes. So we recruited college students, young adults from community colleges and four-year colleges.

We tried to recruit equal proportions of current cigarette

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smokers, former smokers and experimenters of cigarettes, and never smokers. So 65% of the sample was female, and sample size was relatively small but adequate for us to test our hypothesis. So marketing receptivity was assessed in terms of liking of e-cig ads and receptivity to e-cig promotions. And e-cig harm perceptions, meaning perception studies, e-cigs are less harmful than cigarettes, were assessed to 20 items possessing beliefs that e-cigarettes are less harmful than cigarettes, are healthier than cigarettes, and e-cigarettes help smoking cessation. So these items were created based on previous literature on modified risk tobacco products.

So this is the model we tested with low e-cig harm perceptions as a potential mediator against the preliminary study, and it's cross-sectional data, but we went ahead and tested mediation. So we found that interpersonal influence, as assessed through family and peer use of c-cigs, had a direct and significant effect on past 30-day e-cig use. And those e-cig harm perceptions had direct significant effect on past 30-day e-cig use, and as expected, marketing receptivity has indirect effect on past 30-day e-cig use via low harm perceptions, low e-cig harm perceptions. So this has been published.

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So now I'm going to talk about the experimental study. In both the cross-sectional study and the experimental study, our goal has been to test empirically whether e-cig marketing -- whether e-cigs are marketed as safer alternatives to tobacco products, tobacco cigarettes, and whether e-cigs are specifically marketed to attract youth and young adults. So those have been our goals. So, in the experimental study -- it's still an ongoing study, so I'm just going to present part of the data today. Our goal has been to determine the processes, explicit and implicit processes, that mediate the effects of e-cig advertising on e-cig use susceptibility among young adults, specifically current nonsmokers of cigarettes.

And by explicit processes, I mean conscious beliefs and attitudes. And by implicit processes, I mean unconscious, relatively unconscious, you know, automatic, spontaneous attitudes. And this line of our work has been formed by the dual process framework which postulates that both conscious and relatively unconscious processes independently shape decision making, specifically in health behavior.

So the participants of this study, according to the data that I'm going to present today, were nonsmokers who had never tried electronic cigarettes. And by nonsmokers, I mean those

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who had never tried cigarettes before and those who had experimented with cigarettes, but they're not current users, who had tried, you know, less than 100 cigarettes in their lifetime and none in the past 1 year. So what we did was, this is a lab study, we brought in participants and randomly assigned them to either view e-cig ads or control ads. There are two types of e-cig ads. One that we labeled "health" and another that we labeled "social." And health e-cig ads were six ads that we randomly picked from a pool of pretested ads.

We pretested the ads using qualitative studies, and these ads were found to include direct and indirect messages with reduced harm and health benefit claims. So we randomly selected six ads from a pool of pretested ads containing health-related messages. And we mixed them with ads of everyday products like cooking oil, toothpaste, pair of shoes, and we exposed participants in the health condition to these health ads plus everyday -- ads of everyday objects.

And, similarly, we exposed those in the social condition to social ads. These were ads that were pretested. We randomly selected six ads from a pool of pretested ads that were found to include messages that projected e-cigs as glamorous, fun, sexy products that enhanced your self-image or

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social life. And the control condition included 20 ads of everyday objects who matched in quality with both types of experimental ads.

And immediately after viewing the ads, participants completed measures, explicit and implicit measures, of various kinds. So these are examples of ads, these are examples of ads included in the health condition. And these are examples of ads included in the social condition. So the explicit measures in the study included, you know, the same 20 items of harm perceptions that assessed perceptions that e-cigs are safer and healthier alternatives to tobacco cigarettes. And positive social outcome expectancies, these were 13 items assessing beliefs that e-cig use results in positive social outcomes; this scale had been validated by us in a previous study. And e-cigarette use intentions. And implicit measures that we used were adapted by us to assess implicit attitudes towards e-cigs, and these were Implicit Association Test and Affect Misattribution Procedure.

Now, Implicit Association Test, we adapted it specifically to assess spontaneous (implicit) attitudes towards e-cigs as safer alternatives to cigarettes. And so the way the task works is participants are asked to sort word or picture stimuli

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into one of the categories on the top. And the idea is that individuals sort the stimuli to categories faster when they are compatible in their mind and slower when they're incompatible in their mind. So then we used Affect Misattribution Procedure to assess general spontaneous attitudes towards e-cig. Or positive affective reaction towards e-cig. So was just general, it did not pertain to assessing e-cig, attitudes towards e-cig as safer alternatives to cigarettes. It's a general pleasant affective reaction. That's what it assessed.

So the way this task works is -- it works on the basis that individuals tend to misattribute affect from one source to another under conditions that are ambiguous. So the task consists of flashing or presenting primes, pictures of e-cig cigarettes very rapidly on computer screen and then flashing Chinese characters or novel, ambiguous geometric shapes right after the prime pictures.

And participants are asked to rate the Chinese character or the fractal image on the basis of pleasantness, whether they find it pleasant or unpleasant. The idea is that the affective reaction created by the prime is misattributed to the Chinese character, and that is supposed to happen outside of awareness.

So we expected that participants in the health condition

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would score higher on self-reported harm perception, explicit measure of harm perception, and implicit attitude test, or Implicit Association Test, compared with participants in the control condition. And participants in the social condition will score higher on positive social outcome expectancies and implicit attitude as assessed through AMP compared with participants in the control condition.

And the participants in the study were, you know, those who had never smoked cigarettes and those who had experimented with cigarettes were equally represented, and most of them were ethnically diverse, and 64% of them were female. And there were no differences among conditions in demographic characteristics or smoking history.

So when we compared harm perceptions between control and health conditions, we did not find any significant difference; the effect was small. However, when we compared the implicit attitude, we found significantly higher implicit attitudes towards e-cig as a safer alternative to tobacco in the health condition compared to the control condition.

I lost one of the slides, two slides.

DR. DRESLER: Don't know how to fix that.

DR. POKHREL: Two slides.

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DR. DRESLER: Two slides are missing?

DR. POKHREL: Yeah, yes.

(Pause.)

DR. DRESLER: We just have two blank ones, so I'm sorry.

DR. POKHREL: So we found similar effects in the social condition as well. We did not find any significant difference in explicit attitude, but we found a significant difference in implicit or spontaneous attitude towards e-cig.

And when we compared the association between variables and openness to use e-cigs in the future, we found that those assigned to health conditions were significantly more likely to report openness to use e-cigs relative to those assigned to control condition, and those assigned to social condition were significantly more likely to report openness to using e-cigarettes in the future than those assigned to the control condition. And when we looked at associations with an implicit attitude and openness to use e-cigs in the future, both IAT and AMP were significantly associated with openness to use e-cigs in the future with explicit attitude measures included in the model.

So, to conclude, it appears that exposure to e-cig ads may affect conscious as well as relatively unconscious attitudes

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favorable to e-cigarette use, even among those young adults who are current nonsmokers and who had never tried e-cigs. And e-cigs are marketed, are being marketed implicitly if not explicitly, as reduced-harm alternatives to tobacco cigarettes. And e-cigs are marketed to attract youths and young adults by promoting spontaneous association of e-cigarette use with appealing self-image.

Thank you.

(Applause.)

DR. DRESLER: Okay, thank you.

And our next speaker will be Dr. Laura Gibson from the University of Pennsylvania, speaking on E-Cigarette Use, Cognitions, and Ad Exposure: Interim Results from the University of Pennsylvania Youth and Young Adult Survey.

DR. GIBSON: It's a mouthful, yes. But I'm very glad to have the opportunity to share with you some of our initial results from an ongoing study that's going to be about 3 years long, so this is really just the beginning of things, work that we've done at the Tobacco Centers of Regulatory Science with my colleagues Jiaying Liu, Kirsten Lochbuehler, and Bob Hornik.

So today's talk is going to have two parts. The first, I'm going to talk about the patterns of e-cigarette use for 13-

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to 17-year-olds and 18- to 25-year-olds. I know that was mentioned this morning, too, but I want to set it up for the other work I'm going to present. And how those patterns of use are related to their patterns of cigarette use.

And the second part will be about whether or not e-cigarette marketing impacts use among never cigarette smokers, again, separated by these two age groups. And if so, how is e-cigarette marketing having an impact? We have a little taste of that at this point. As I said, this is ongoing, so we'll have a better understanding in the future.

So the CDC released the Monitoring the Future data a few months ago that current e-cigarette use among middle and high school students had tripled from 2013 to 2014. If you look at the actual data, the high schoolers in 2014 wound up at 13% of use in the past month and middle schoolers at 4%. The purple dotted line that I'm showing is our data for high schoolers. So we have a little bit less in 2014. We had 6 months of data there. And then we have about 4 months of data in 2015, but it's still in the right ballpark. Ours was a phone survey, and theirs is paper and pencil, so you might expect to see a little bit lower response there. But it was good to see we're in the right ballpark.

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This is a schematic of our survey design. So we started data collection in June 2014, and we're getting about 300 cases every 4 weeks for the next 3 years, and after that first interview, 6 months later we go back to the same people and try to get them to talk to us again for a second interview.

Right now we're getting about a 40% response rate. But the data I have is through April, and so there's not enough of that re-contact data to present those analyses today, so I'm going to present the cross-sectional data we have for 3,200 cases, pretty much equally split between the 13- and 17-year-olds and the 18- and 25-year-olds.

Here's the sample characteristics. Un-weighted. All the rest of the analyses I'll be presenting are weighted to national sample. It was a nationally -- sorry, there's one piece I -- very important piece I neglected. It's nationally representative data samples that's a phone survey of random digit dial, so we're trying to get all across the country. You can see a 50/50 split on our gender. We used parent education as a stand-in for socioeconomic status, and in terms of race-ethnicity we have 24% Hispanics and 51% non-Hispanic whites, which kind of fits with what you would expect from a younger population.

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Finally, 30-day tobacco use; I have the list there. And as you might expect, it's a little more telling when you look at it separately by the different ages, the 13- to 17-year-olds versus the 18- to 25-year-olds, which we'll do now.

So looking at e-cigarette awareness, we asked -- specifically, we tried to -- even though this is a phone survey, so we have a lot of stuff we're trying to pack into a short amount of time, we did try to say have you ever heard of vaping or using e-cigarettes to try to get at the fact that it's not just cigalike products. And 70% of 13- to 17-year-olds and 79% of 18- to 25-year-olds expressed awareness. If they hadn't expressed awareness, we gave them a little description of what we were talking about in further detail and asked if they'd ever tried it.

And our ever tried numbers are here with, again, more 18- to 25-year-olds trying them, 13- to 17-year-olds, and the same pattern for current use. And so this 8% for the 13- to 17-year-olds includes the middle schoolers, some middle schoolers in there with the high schoolers, so that's why we're not at the same numbers I was showing you earlier.

But similar to the CDC's report from the Monitoring the Future survey, we are seeing that for the 13- to 17-year-olds,

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more have ever tried e-cigarettes than have ever tried cigarettes, and we see an opposite pattern for the older group. So we're very curious about this pattern for the 13- to 17-year-olds. Why might that be? And one explanation is, well, they're just trying it, and they're not actually intending to use it; it's just sort of a novelty.

One piece of information I think is useful in understanding this is looking at ever use for both e-cigarettes and cigarettes, and then intention to use that same product in 6 months. If you've ever tried an e-cigarette, you're more likely to intend to use it in the future than if you've ever tried a cigarette, and this holds for both the 13- to 17-year-olds and the 18- to 25-year-olds. And it also holds when we look at just current use, not just ever use.

As you might expect, e-cigarette use is also associated with tobacco cigarette use in our sample. Here I have the 13- to 17-year-olds in blue again, and the 18- to 25-year-olds in red, and it's looking at the combination of if they've ever tried tobacco cigarettes and ever trying e-cigarettes. And so you see yes.

Trying cigarettes is strongly associated with trying e-cigarettes for 13- to 17-year-olds, are 66%, 66% who had ever

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tried cigarettes, ever tried e-cigarettes, whereas only 11% of the never tobacco cigarette users. And it's the same pattern for 18- to 25-year-olds. But you see that there's very few who have ever tried tobacco cigarettes with the 13- to 17-year-olds.

And so when we look at that same data within those who have ever tried e-cigarettes, as the panelist was talking about before, for the 18- to 25-year-olds, there's a much smaller number who have ever tried e-cigarettes who are never tobacco cigarette users. Here, half of the youth who have tried e-cigarettes have never tried smoking. So we really focused -- leaving aside the cigarette smokers, let's look at these never cigarette smokers and their usage of e-cigarettes and how it might be related to marketing.

So data has been presented by Kornfield et al. that by the third -- or the second quarter of 2013, \$28 million has been spent on e-cigarette advertising. And as was mentioned, the RTI study was showing that advertising is getting to the youth and young adults. Our study also, when we asked people to self-report how much e-cigarette exposure, ad exposure they have had across a variety of sources, 54% of the 13- to 17-year-olds have been exposed and 61% of 18- to 25-year-olds.

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Again, that's self-report. But if we look at that self-reported ad exposure, and so three buckets -- no ad exposure, weekly or less, and more than weekly -- and see how that's associated with current e-cigarette use just among the never cigarette smokers, we see an association for both age groups with the more exposure you have, especially more than weekly, you are more likely to have used an e-cigarette.

Of course, this falls into the problem of selection bias that you're using e-cigarettes, you're more likely to pay attention to the e-cigarette ads. So perhaps a more conservative test of this would be to look at e-cigarette intentions among those who have never used cigarettes and those who have never used e-cigarettes. So that's what we did next.

But, first, I want to just show you that those never users are still being exposed to the e-cigarette ads. So, for 13- to 17-year-olds, in terms of any exposure, whether it's weekly or less or more than weekly, 53% have been exposed. And for 18- to 25-year-olds in this group of never users was 55%.

And when you look at their intention to use e-cigarettes in the next 6 months for these never e-cigarette users, never cigarette users, by exposure just for the 13- to 17-year-olds, we're seeing an effect of exposure. And this is adjusting for

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confounders you would expect: gender, race, the number of close friends who use e-cigarettes, people in their households who use e-cigarettes, household vaping rules, sensation seeking, and the grades that they're getting.

So this is finally having some association that where we see a difference in terms of what's happening with 13- to 17-year-olds versus 18- to 25-year-olds, which might kind of connect back to that earlier slide. One piece of information that might be useful in trying to understand this, as I said, we're just beginning to look at this, but one association we also saw with exposure was when you look at the descriptive norm, so your belief that half or more of your peers use e-cigarettes, there was an association there in terms of exposure. So the more you're exposed to ads, the more you believe that your peers are using -- and this is both for the 13- to 17-year-olds and the 18- to 25-year-olds. Again, the same population adjusting for confounders.

But when you look at the association of this belief that peers use e-cigarettes with the intention to use e-cigarettes, here I've broken out the belief about peers into all the four groups that we measured, not just collapsing across about half and most and none and a few.

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You can see that it's the 13- to 17-year-olds who, if they have this belief that their peers are using e-cigarettes, are more likely to intend to use e-cigarettes, and we're not seeing that association for the 18- to 25-year-olds.

So from this work, which is looking like a mediation analysis, but we have not yet done it, but it seems each of the pieces is there. For 13- to 17-year-olds, we're seeing an association between e-cigarette ad exposure and the belief that peers are using e-cigarettes, and that belief is associated with their e-cigarette intention, so it may be mediating this relationship between e-cigarette ad exposure and intentions to use e-cigarettes among never cigarette or e-cigarette users; whereas for the 18- to 25-year-olds, although we see a relationship between ad exposure and the belief that peers are using e-cigarettes, it's not translating into their intentions to use among this never cigarette or e-cigarette user group.

So, in summary, yes, 13- to 17-year-olds in our dataset are trying e-cigarettes more than tobacco cigarettes; it's a nationally representative sample, so we feel pretty confident. Also been seen in other places. And half of the 13- to 17-year-olds who try e-cigarettes have not tried cigarettes. Second bullet point is something about addiction that I decided

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to leave out in the interest of time.

They're also more likely to intend to use them again after trial than they are to intend to use cigarettes. And e-cigarette marketing is associated with e-cigarette use for never smokers, and perhaps more importantly in looking at the intention analysis in terms of the ability to draw causal inferences, the marketing associated with e-cigarette intention for 13 to 17 never users of e-cigarettes or cigarettes, it showed an association for the 13- to 17-year-olds, not for the 18- to 25-year-olds. And descriptive norms may mediate that association.

So our next steps are to get that additional data so that our analyses will have more evidence for proper temporal order and no alternative explanations, so we're going to have 2 more years of survey data; that will give us more power. We'll also be able to look at changes over time. Our weekly samples, we really sample on a weekly basis so that we can combine it at any point in case there's something that happens in the world so that we could switch up how we're making our 4-week groups.

We're adding objective measures of exposure to e-cigarette ads. We have access to the Kantar ad data, but it doesn't include vape shops but at least will give us some external

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measure of exposure to e-cigarette ads. And, of course, using the panel data to adjust for individual prior intentions to use e-cigarettes and other alternative explanations.

So, in conclusion, if the data patterns we see are maintained in more definitive analyses, regulation of e-cigarette marketing might be expected to reduce the initiation of use of e-cigarettes among 13- to 17-year-old never cigarette or e-cigarette users. And ads which lead 13- to 17-year-olds to believe that their peers are e-cigarette users may be a particular concern.

Thank you.

(Applause.)

DR. DRESLER: Thank you.

Okay, our next speaker in this panel is Dr. Matthew Farrelly from RTI, and he will be speaking on a Randomized Trial of the Effect of E-cigarette Television Ads on Intentions to Use E-cigarettes.

DR. FARRELLY: Thank you. Happy to present, especially the other speakers really set this one up, I think, for me.

I won't belabor some of the background which has been covered pretty well. We know e-cigarette use among adolescents is increasing rapidly. Expenditures on marketing and

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advertising have also increased recently, including adolescents' exposure to television advertising. So we set out to answer the question as to what extent is advertising influencing adolescents' interest in use of e-cigarettes.

So about a year ago, we conducted a survey of just over 5,000 13- to 17-year-olds with a convenience sample online panel. We screened for past use of e-cigarettes and intentions to use e-cigarettes in the future. And so about 26% of the sample had already tried e-cigarettes; the rest had not. Both groups were randomized to either be in the treatment group or the control group. The treatment group saw four 30-second television advertisements for e-cigarettes, and then the control group, they saw those ads at the very end after they completed the survey so that we could get data on receptivity and prior exposure for all of the study participants.

But to get to the ads, the four ads, we had to make some choices. We pretested a number of advertisements, youth from the same panel, but samples from the two studies did not overlap. We had 1,000 adolescents. We tested 13 ads; they all had been on the air previously and -- or frequently or had a broad audience, like one that was on the Super Bowl.

So we selected 4 from those 13 because they were rated the

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highest in terms of receptivity among the adolescents. So we have two 60-second advertisements for blu e-cigarettes, one for NJOY, and one for 21st Century, which is less well-known but tested very well. And similar to the previous presentation, especially on the website themes, many of the same themes show up in the television advertising, including that e-cigarettes are safer, they can be used where cigarettes are not allowed, it doesn't affect those around you, and using an e-cigarette feels like smoking a conventional cigarette, and it gives you a sense of freedom and independence.

So our key measures for the study were intentions to use, adapted from the Pierce scale. In this case we dichotomized it, definitely not -- or probably not. And then we looked at the perceived benefits of e-cigarettes using a 5-point scale. So it's similar to those themes in terms of not affecting those around you, it's a safer alternative, it's a good way to express your independence, and they're less toxic.

Another set of measures, we used a 7-point semantic differential response scale. So because this is a web survey, we were able to present the two ends of each of these from un-enjoyable to enjoyable, dangerous/safe, cool/not cool. It's a 7-point scale, and then they can choose. And then how harmful

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are e-cigarettes and how harmful are cigarettes were also assessed on a 5-point scale. So, for the analysis, this is all part of the forthcoming -- it's an in-press article at the *American Journal of Preventive Medicine*, so I can't give all of the results because it's embargoed. I'm going to give a subset, but you'll still get the flavor of the study. To make sure the dramatization worked well, we tested across a number of demographic characteristics, and the only things that were slightly different were current cigarette use and race/ethnicity. They're marginally significant.

So, to test the effect of the treatment, we -- most of the outcomes were dichotomous, so we used logistic regression in those that were continuous linear regression, and because of these two differences in the sample, we accounted for race/ethnicity and current cigarette use, although it really had almost no difference.

I was worried about this being a bit of an eye chart. I tried to blow it up as well as I could, but -- so this is looking at "probably" or "definitely yes" to:

- You can use e-cigarettes in places where smoking is not allowed. A significant difference there of about 13 percentage points between the treatment and the

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control. The treatment is the green, if you can see it, on the left-hand side where we just present the percentages.

- People can use e-cigarettes without affecting those around them. Also about a 13 percentage point difference.
- E-cigarettes are a safer alternative. Significantly different, not as big of a difference.
- They're less toxic. Smaller difference.
- And then using e-cigarettes is a good way to express your independence. About an 8 percentage point difference.

So looking at the logistic regressions for all of these, the odds ratios are significant in all cases, ranging from about 1.1 to 1.9.

So some of the other select results:

Will you try an e-cigarette soon? There was a statistically significant difference, 11.5% for the treatment group versus 7.6% for the control, an odds ratio of about 1.5. Compared to the control group, those in the treatment group are more likely to report that using e-cigarettes is smart, healthy, safe, and those we dichotomized using that 7-point

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scale I mentioned before at responses 5, 6, and 7, so the upper end of that. And then the treatment group was also associated with a decrease in perceptions of harm for e-cigarettes but not for cigarettes, which we anticipated.

So this study is a little bit different than some of the others because we were able to randomly assign adolescents to the different groups. We find similar findings, though. Not surprising, the e-cigarette advertising works. It's influencing youth, they're having more favorable attitudes, intentions to use e-cigarettes in the future, and in general, just having more positive feelings about this product that they were maybe not that familiar with prior to the study.

And I think when you put that in context with the increasing trends, the increasing advertising and marketing expenditures, the documented increase in exposure among adolescents to the advertising, you know, this study makes a lot of sense that we see these kinds of associations. And remember, it's just for -- they were only exposed to four television advertisements, so the dose is relatively small, and despite a relatively small dose, you saw pretty consistent and large shifts in beliefs about the product and also statistically significant increase in intentions to use in the

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future. So left unfettered, this continued advertising won't be surprising if we see continued growth in e-cigarette intentions and use among adolescents.

So, in summary, the advertising seems to be working as it's intended, increasing adolescents' curiosity, creating positive beliefs about the product, and increasing intentions to use.

Wanted to acknowledge that the funding for the study was supported by the Department of Health of -- Florida Department of Health. And my colleagues, a few of them are here today, include Jennifer Duke, Erik Crankshaw, Matt Eggers, Youn Ok Lee, Jim Nonnemaker, and Annice Kim. And Lauren Porter from Florida Department of Health.

(Applause.)

DR. DRESLER: Good. Thank you, panel speakers. So now the panelists will please come up to the front here. Your name tags are up there, and we'll have some clarifying questions and others. And so same issue. There will be cards, people are passing out the cards, so please write down your questions.

(Pause.)

DR. DRESLER: Let me start off with a question. How does tobacco user status affect receptivity to the e-cigarette

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marketing? So if a person is using the e-cigarettes, how receptive are they to -- if they're already using e-cigarettes, how receptive are they? Does it matter?

(Off microphone response.)

DR. DRESLER: Push the button, please.

DR. POKHREL: I suppose it matters, but we didn't really find differences among e-cigarette users -- oh, we did find differences among e-cigarette users and nonusers as in a cross-sectional study, that those who used e-cigarettes were more likely to be receptive to e-cigarette ads.

DR. DRESLER: Okay.

DR. POKHREL: Yes. So, you know, we need longitudinal studies to really tell. We need longitudinal studies to really be able to tell.

DR. DRESLER: Okay. Do you want to --

DR. GIBSON: I was just going to say the same, that we did see that the more you had used e-cigarettes, the more likely you were to have been exposed, but I think that could be an issue in terms of measurement, because -- well, it's a question of which it is. We don't have the data to speak to just that.

DR. DRESLER: Okay. It makes me think, from the previous panel, it depends on whether they're more susceptible to

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multiple substance abuse, too. So how do you break that apart, too, versus using.

To what extent do e-cigarette advertisements affect attitudes about the product category? So I think you were addressing some of that.

DR. FARRELLY: Yeah, I think for me what was most striking about our study with a pretty brief exposure to advertising, we saw really large shifts in attitudes and beliefs, so for those who work on, say, for example, campaigns to try to discourage cigarette smoking among youth, if you saw a 10 percentage point shift from your advertising, you'd be really excited.

And so to see such significant large shifts in beliefs based on a small exposure suggest that, you know, it's having a lot of influence. And it could be because some are new to the product, don't know much about it, but certainly it was having its intended influence. The themes in the advertising really reflect in the changes in the attitudes and beliefs.

DR. DRESLER: I think, you know, as we talk about the different campaigns that are out there, they talk about dose, and four is a really low dose. It seems like many ads are considered to be targeting kids. What kind of ads are clearly not targeted to kids?

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DR. GRANA: Well, that's a good question. I think that some of that -- so in looking at all the web advertising, for instance, you -- we most often saw really young models being used, and I think that would be aspirational to youth and young adults, right?

But some of the advertising, you know, would be for a middle -- you know, with a middle-aged model just talking about wanting to, you know, quit cigarettes. I mean, if you've seen Chantix commercials, for instance, or some of the NRT commercials, they'll show actual, like, older people -- or I mean, this could be my age.

DR. DRESLER: Middle age, middle age.

DR. GRANA: Thirties to -- yeah, middle age and older trying to quit smoking and talking about how -- or trying to, you know, improve their health, and so those would be more focused on a non-youth audience.

DR. GIBSON: And just an analogy from the alcohol literature. There's some evidence that if you focus on the product in terms of wine, kids are less interested in that. They're not interested in hearing about the product itself; they're more interested in the other types of appeals.

DR. DRESLER: So that very much goes to the next question

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I had: Is it possible to advertise the electronic nicotine delivery systems without appealing to youth?

And so I heard the recommendation, put a middle-age or older --

(Laughter.)

DR. DRESLER: A middle-age person up there.

DR. GRANA: I'm definitely not consulting to market any electronic cigarettes, but I just think that the -- I guess I'll address a little bit more of the contrast, too. But using these, you know, glamorous celebrity youth models and also especially, I think, of interest, and we saw it previously used in tobacco industry promotions, are these accessories and bright colors and jewels on the product and things like that. I mean, they're really designed to attract a very young aspirational audience. So that is what not to do if you're trying to not attract youths.

DR. POKHREL: One could argue that the ads put out by MarkTen, for example, you know, without models, the plain white and red ads, one could assume that those contain implicit health messages but not, you know -- they're not catering to young people, one could argue. But it's not been empirically tested, of course.

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DR. FARRELLY: I think one thing to keep in mind, though, is because this is still a relatively new product and there's a lot of buzz about it, you know, one of the ads that we presented was 21st Century. That commercial is more like an infomercial, and it tested just as well in terms of receptivity as the blu e-cigarette ads, which are meant to be very much more, you know, about the lifestyle, not just the product.

So I think that in the context of where we are right now, I think it's pretty hard not to get teens interested if you're mentioning all these different potential benefits, even if it's done, like, an infomercial. So maybe that will be different 5 years from now, but right now I think it's -- you have to keep that in mind.

DR. DRESLER: Expand on that because what I heard you say is it's talking about the benefits, so this is the benefits for teens.

DR. FARRELLY: Well, I think that they, you know, the products talk about being able to use it anywhere, for example, that you can use it without bothering people around you. So they're sort of touting -- the message themes are contrasting with cigarettes and giving, you know, possibilities to you where you can use it, for example, give you a sense of freedom

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and independence, which may be aimed at adult smokers trying to quit, but it may also just be trying to say, hey, you can use this anywhere.

DR. DRESLER: Okay, all right.

So this is a clarifying question for Dr. Gibson. We've seen that Hispanic youth are the biggest users of e-cigarettes. So Hispanic youth are the biggest users of e-cigarettes and that they are more likely to use e-cigarettes and cigarettes. Do you find anything unique or significantly different about Hispanic youth compared to other race or ethnicities?

DR. GIBSON: I'm familiar with that statistic, I believe, and have not yet looked at it in our data. But we do have a large enough sample that potentially, once we have more data, we could look at that difference.

DR. DRESLER: I think that was a question we had, and I think it was the first panel, is what sort of racial or ethnic differences, and the panel kind of came back saying we don't have enough data yet to really say. So --

DR. GIBSON: So then -- yeah. I'm not sure if what I'm remembering is some data analyses I have run or something, but yes, not yet decided.

DR. DRESLER: Okay. All right. Is there any evidence

about how marketing of e-cigarettes affects attitudes about conventional cigarettes? So you were just -- um-hum?

DR. FARRELLY: So, in our study, there was really no influence of the advertising on perceived harmfulness or really any outcome related to, like, intentions to use cigarettes in the future. So we saw really no influence on conventional cigarettes in our study.

DR. DRESLER: Okay. Anyone else?

DR. POKHREL: I haven't really looked at in my study. I haven't really looked at intentions to use cigarettes. Because I've been focusing on nonsmokers and experimenters, I have not assessed intention to use cigarettes.

DR. DRESLER: Okay.

DR. GRANA: There is published research showing some of the cueing effects of viewing e-cigarette advertising. So it is possible, although I'm not going to define that, but -- in relationship in that study. But I think it's still a very open question and a big concern that viewing some of the -- especially simulated smoking behavior in these television commercials, for instance, could and has had cueing effects for urge in smokers.

DR. DRESLER: To follow up on that, this is a question

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that I had heard before, that when you see the e-cigarette once and the competition for having the amount of smoke in the exhaled smoke, that's one of the things saying, oh, don't have exhaled smoke because it's a trigger for people. Is there any work looking at that?

DR. GIBSON: Not yet completed.

DR. DRESLER: Okay. So it's in the works. All right.

Earlier, Dr. Shiffman speculated that marketing e-cigarettes as cessation aids might decrease youth appeal. Are you aware of any data to that effect?

(No response.)

DR. DRESLER: So there's no information about that, okay.

Dr. Pokhrel, it seems like the IAT tested overall favorability or good/bad valence. How are you making the link to reduced harm specifically?

DR. POKHREL: Because the stimuli -- the word "stimuli" that we used for categorization were all related to health and reduced harm properties.

DR. DRESLER: Okay. If e-cigarettes are indeed safer, as most agree, isn't a shift towards accurate perception a good thing rather than a problem? So if everyone thinks that e-cigarettes are further on the more safe side than less safe

side compared to combusted, isn't a shift towards that perception a good thing rather than a problem?

DR. FARRELLY: Everyone is hesitating on that one.

(Laughter.)

DR. FARRELLY: I mean, I think that -- well, I looked at adolescents, and you know, the CDC data shows that e-cigarette use has now surpassed conventional cigarette use. So I think one thing that's hard to do is control the impact of the message. So, yes, you might make it more accurate, but if the end result still is that e-cigarette use is higher than conventional cigarette use, what progress have you made? So I think that's something to keep in mind.

You know, I think that used to come up with smokeless and cigarettes. How do you message, you know, that oh, it's safer over here, but you know, not get more people to then take it up? I think that's the part that's really difficult, and I'm no expert, but I don't think that many people think it's a good idea for more adolescents to have exposure to nicotine. So I think it's hard to do that because of the way media messages spill over boundaries.

DR. POKHREL: So the question was if e-cigs are safer than cigarettes, then it's good that people believe it's safer than

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cigarettes. Is that the question?

DR. DRESLER: Right. There is a presumption that it's less harmful, that it's safer.

DR. POKHREL: Right.

DR. DRESLER: Why not have people --

DR. POKHREL: And if they're marketed as being safer than cigarettes. So I guess it really becomes a question for regulations, so they'd be regulated as modified risk tobacco products. In the absence of regulations -- you know, they're not regulated as modified risk tobacco products. So is it okay to advertise them as modified risk tobacco products?

DR. DRESLER: I'm asking the questions here.

(Laughter.)

DR. POKHREL: So I guess, too, the regulations are not in place. It's not okay, you know, to assume that they are safer than cigarettes, right?

DR. DRESLER: Thank you.

DR. GRANA: Until they've fully been evaluated, you're saying?

DR. POKHREL: Yeah.

DR. GRANA: Can I add one more thing to that? So the only thing -- one thing I think we have to remember is that although

it may turn out to be true, what most people assume, of course, that e-cigarettes are probably less dangerous than tobacco cigarettes, tobacco cigarettes are extremely dangerous. And so one thing to consider is that we don't fully have an appreciation of the health effects of e-cigarettes.

In addition, we already know that nicotine is being provided to the user from those products. And in particular with adolescents, that's -- it's a really critical window of brain development, for instance, and other addictive behavior formation, and there are lots of other drug experimentation that could be interactions, too.

So I think that there is -- you know, correcting that perception of harm, if it leads to really increased uptake, especially among adolescents, can have very negative health effects for those adolescents and public health in general.

DR. DRESLER: Okay, how does the tobacco user status affect receptivity to e-cigarette marketing? Thank you, if someone would address this one. So if the tobacco user -- they're a user of tobacco, how does that affect their receptivity to e-cigarette marketing? So a user versus a nonuser.

DR. POKHREL: I think receptivity is higher among smokers

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because most -- it seems to me, and based on my data as well, it seems like tobacco users are looking for safer alternatives to tobacco, so they are more receptive to e-cig marketing.

DR. DRESLER: So they're believing the marketing, that it is less harmful than a cigarette?

DR. POKHREL: Yes.

DR. DRESLER: Okay. Anything else?

(No response.)

DR. DRESLER: Okay, how do we evaluate the impact of advertising relative to other factors that affect youth tobacco use? Aren't youth pretty savvy to marketing attempts already? So how do we evaluate the impact of it relative to other factors?

DR. FARRELLY: Well, I think you do that like we do all other advertising campaigns. And it's not easy, but you try to control for a lot of the factors like Laura did in her study, to the extent that there's variation in exposure across media channels and over time, that we can link to surveys of youth. You can start to tease that out.

So I think it's challenging, but that would be a complement to experimental studies like I just did that show that it is having an influence. So we have that, and then we

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just need to apply that to the real world to see how does it contribute above and beyond other factors. So it's challenging, but not impossible.

DR. DRESLER: Other comments on that?

(No response.)

DR. DRESLER: Okay, how does marketing relate to the language people use to describe e-cigarettes and their use? For example, vape, vaping, vaper. Does it matter what language you use in the marketing?

DR. GIBSON: The most I can say about this is, as we were trying to develop our questions and being aware that using e-cigarettes was not going to include everything, we wound up using particular words in our description, vape pens, e-hookah, or e-cigs, because of Google trends, in terms of looking at which words were most popular in terms of searches. So that's not perfect, but at least getting at what people are using to look up. I'm not sure how that relates necessarily to how e-cigarette companies are marketing. But at least in terms of a way to get at which terms to use, that's an idea for people.

DR. DRESLER: Okay. Okay, under the Master Settlement Agreement, cigarette advertising was restricted to adult print magazine. Forgetting the First Amendment issues --

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(Laughter.)

DR. DRESLER: I'm not sure how you do that, okay, but forget the First Amendment issues, is that an applicable model to restrict e-cigarette advertising, or would that unduly restrict advertising adult shifts to e-cigarettes from cigarettes? So, you know, if you say that you're going to very much limit e-cigarette advertising, how much will that inhibit the potential impact, positive impact of getting combusted to e-cigarettes for adults? Is that making sense?

DR. GIBSON: Yeah, but it doesn't seem to have limited adults from smoking cigarettes. So I feel like if we're trying to reach those same people, that the channels that are there would probably work as well for e-cigarettes.

DR. DRESLER: Okay.

DR. GRANA: Although marketing restrictions do contribute to a lowering of prevalence. But I think it's important to remember that cigarette advertising on television has been restricted since the 1970s, and similar restrictions could be theoretically put into place for e-cigarettes. And I think we've seen pretty good data today that viewing these advertisements does have an effect on attitudes and favorable attitudes, especially among youth. So thinking about marketing

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restrictions, I'm definitely not a legal scholar to parse out the First Amendment issues, but some marketing restrictions would be potentially needed.

DR. DRESLER: And so those marketing restrictions would inhibit kids from changing their opinion, but getting adults to --

DR. GRANA: I think it's an empirical question that more research could try and simulate and tease out.

DR. DRESLER: Okay. All right. Well, with that, those are the questions that I have for you. No more questions coming in. Thank you very much, panel and speakers. Thank you.

(Applause.)

DR. DRESLER: Okay, so it is now time for a break, a 15-minute break. So we'll start at 2:45, okay? Thank you.

(Off the record at 2:30 p.m.)

(On the record at 2:46 p.m.)

DR. DRESLER: Okay, so our last-but-not-least session for the day is on Knowledge, Attitudes, and Beliefs. And our first speaker will be Dr. Bonnie Halpern-Felsher from the Stanford University School of Medicine, speaking about Assessing Adolescents' and Young Adults' Perceptions of Health Risks,

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Social Risks, Addiction and Benefits from Tobacco Products.

DR. HALPERN-FELSHER: Oh, you remembered to lower it for my height challenge. Thank you.

Hi, everybody. Thank you. I'm delighted to be here and talk about something that's very passionate to me, which is adolescents' and young adults' risk and benefit perceptions.

I have nothing to disclose in terms of financial or conflict of interest, but I do want to acknowledge my research team and in particular the funding. I am the PI on one of the projects within the UCSF TCORS.

So why are we talking about risk perceptions, benefit perceptions? How are they important? Well, first of all, they're included in most theories of decision making. We heard about this briefly earlier today. Health belief model, theory of planned behavior, other models of decision making really talk about the importance of understanding perceptions and attitudes in predicting behavior.

Further, if you look specifically at tobacco use, cross-sectional studies show that people who smoke perceive less health and social risks and greater benefits from smoking cigarettes than do nonsmokers.

Further, we've seen, and our own lab has shown, that

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perceptions of low-, long-, and short-term health risks and greater perceptions of benefits actually predict the onset of behavior. And I cite some of the references there. There are many others. But, clearly, perceptions are very important in not only understanding behavior but in predicting.

But there are gaps in the literature. First of all, a lot of the studies looking at risk perceptions just focus on general harm. So how harmful is this? How much harm might it cause you?

Few studies really focus on specific risks and benefits associated with e-cigarettes or other tobacco products. And I'll show you more about this in a minute. But by specific risks and benefits, I mean not just general harm but specifically, could it cause lung cancer? Could it cause a heart attack? Could it lead to addiction? Might it make you look cool? And so on.

There's also a need for studies that assess perceptions of both risks and benefits across tobacco products, in order to better understand the current landscape of tobacco use, including e-cigarette use.

So the aims of the study that I'm going to talk to you today are to determine adolescents' and young adults'

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perceptions of long- and short-term health risks, short-term social risks, addiction, and perceptions of benefits across five different tobacco products, certainly e-cigarettes, but also chew, cigarettes, cigars, and hookah; and also to look at whether the patterns here vary by age, gender, ethnicity, and use of tobacco.

So this is an ongoing prospective longitudinal study, and I'm just going to present some of the data from Wave 1. We have 1,000 9th and 12th -- will have 1,000 9th and 12th graders who are being followed twice a year for 5 years.

And just to give you the breadth of the information that we have, although I'm going to focus on the perceptions today, but we are going to also have a lot of contextual measures. Somebody was asking about peer and parent use. I don't have the answer for you, but we have those data. We have a lot of inclusion of pro- and anti-tobacco marketing efforts, receptivity to marketing, receptivity to peer use, and so on. And like I said, five different products we're looking at. And we also have included in our survey a lot of questions, mostly on Wave 2, which we're just starting now, on flavored products.

So we use a number of different measures of risk perception that I'll show you in a minute. But one of the key

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ones that we do is we ask people to imagine a situation, so that way -- we call this something I've published many years on, called conditional risk assessment, conditional benefit perception. So you put people in a particular situation, ask them to imagine that situation, and then ask them about the risks and benefits that might result.

So imagine that you just began using the following product. We list the five products. You use the product about two or three times each day. Sometimes you use the product alone. Sometimes you use it with friends. And the reason why we do alone or with friends is youths' perceptions actually vary, often incorrectly, based on social situations that they're in. So we wanted to kind of minimize the questions that adolescents are raising in their head of, well, what are you talking about in that scenario? And this has been piloted many, many times and published many times. And then we ask them for the risk perception.

So I won't read these all out loud, but you could look at them, the different kinds of perceptions that we asked. We asked including the short- and long-term health risks, the social risks, the benefits. And then, in addition to just asking about addiction, we have a number of pharmacological and

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addictive effects that we're looking at. So still using at 5 years, easy to quit, feeling jittery, having better concentration, stressed, and buzzed.

So far we have a sample of 643 participants, and you can see it's broken down. We do have more females than males. This is a California-based sample, by the way, school-based recruitment. There are six aged 16. I'm not going to show you the data broken down between 9th and 12th graders today, but I will look at -- just show you whether there is by age in general. And then you can see, similar to the California population, we have about 40% Hispanic, about 25% Asian, and about 26% white.

We also have a qualitative component from a different dataset, but I want to raise it in here because I will give you some quotes around it, which is 24 adolescents who participated in very small focused groups, 2 to 3 to 4 people in a focus group. They were asked very specific questions about perceptions and decision making around e-cigarette versus cigarette versus marijuana.

So those of you who are statistically inclined, I want to quickly tell you about how we analyzed the data. We looked at mean ratings among the products, and we compared them by

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testing a linear model that included a generalized estimation equation that basically accounted for both the repeated measures and the fact that we have multiple schools. So we take away the school effects. We did post hoc comparisons using Tukey-Kramer to control for Type I error. And then we did include age and tobacco use as between-subjects mean effects. But we actually put in ethnicity and sex, but they were not significant, so they were removed from further analyses.

So what did we find? First of all -- and I'm not going to go into a lot of our epidemiological data or use data. People have been doing that all along, and I thought, knowing I was later in the day, I can just jump to the main results. But just a quick highlight to give you some idea of the general patterns of use of those who have used at least one of these products.

And with the exception of marijuana and alcohol, the product that the adolescents in our study are using is predominantly e-cigarette. So if you're going to say have they used any one tobacco and what is the tobacco product they used, it is e-cigarettes.

So, first, we do ask to be able to give some point of

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comparison against national data, as well as the PATH study does ask the more general harm question. So we first want to look at that before we dive into the more deeper analyses of the specific risk and benefit perceptions.

So we ask imagine you use the product below, the five products, two to three times a day, every day. How harmful will this be for your health? And here I'm just comparing cig to e-cig. And what we have is that, probably not surprising, the majority of adolescents, about 74%, thought that cigarettes were harmful to their own health, whereas about 28% thought it was extremely harmful to their health if they used e-cigarettes. And you can see the distributions are pretty different there, in that we have a much wider distribution in perceptions of harm for themselves for using e-cigarettes compared to cigarettes.

You similarly have the results for friends' health. And this is our proxy for secondhand smoke, if you see, but we do have more detailed secondhand smoke questions on there. But this specifically of how harmful, if you were to use an e-cigarette, would it be to your friends' health? And here we have a little more distribution for cigarettes, but generally most people thought that it was extremely harmful for using

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cigarettes compared to e-cigarettes, and that you have "Not at all" being about 15% for e-cigarettes, whereas "Not at all" is 0.3 -- in fact, you can't even see it on there -- 0.3% for cigarettes.

Then we asked how harmful will this be to the environment? We haven't really talked about third-hand smoke today, or third-hand effects. Maybe that's going to come up tomorrow. But basically asking young people how harmful would an e-cigarette be for the environment. And there you similarly see that for e-cigarettes, you see a fairly equal distribution across the five points of the scale, from not at all to extremely; whereas for cigarettes, you see almost half thinking that it is extremely harmful to the environment, and 1.1% thinking that cigarettes are not at all harmful to the environment.

So now let's go into the more specific perceptions. I'm going to walk you through this first slide, and then they're similar across the next few slides. I'm going to show you the data separately for the different categories of risks that we assess. And on the far left, in red, is your e-cigarette. And then if you can't see it, the green is chew, the kind of beige is cigarette, the burgundy or dark brown is cigar, and then the

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blue is hookah. So looking across.

And you can see, across the board, this is asking the question of bad cough, cold, trouble catching breath, and mouth sores. Generally speaking, adolescents perceive e-cigarette to be significantly less likely to cause these health effects, short-term health effects, compared to cigarettes and chew.

And cigarettes and chew are confirming the highest amount of risk, in their mind, compared to the others. The only exception there, which probably doesn't surprise you, is with chew, where there they actually acknowledge that using chew increases their risk of mouth sores. And if you look here, of the percent chance of an adolescent getting -- occurring or experiencing a short-term social risk -- and again, the same pattern that you see. And this is important, by the way. Social risks are very important because, if you think about it, adolescents are fairly aware of the risks of cigarettes. We'll talk about e-cigarettes, which isn't necessarily the case, but for cigarettes -- but they still use them. Why?

A lot of it has to do with social, both social risks and social benefits. Adolescents are social beings. They're very influenced by their peers and what their peers think. So not focusing so much on the health risks, but looking at the social

risks are very important. So here we see, across the board, adolescents think that they are less likely to experience social risks, such as being worse at sports, friends being upset, getting into trouble, or bad breath, if they use e-cigarettes, and that they're more likely to experience these harms if they use chew or cigarettes.

And if you look at long-term health risks, you see something similar. And here we actually included "Never used." I have to attribute this to my 19-year-old daughter who said, well, where's your base? Oh yeah, you're right. Smart kid.

So you really can see the comparison certainly of if they never used. But, again, adolescents think that they're significantly less likely to get oral cancer, wrinkles, heart attack, lung cancer, and tobacco-related disease or death if they were to use e-cigarettes and significantly more likely if they use cigarettes and cigars.

And finally the addictive effects here. And here it's interesting because, again, generally seen for e-cigarettes, they think that they're less addictive. Probably not going to be using an e-cigarette in 5 years. They think that they can quit smoking an e-cigarette, that they're less likely to feel jittery or nervous.

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Interestingly, better concentration was about the same across. Feeling stress was about the same across. But feeling high or buzzed, fairly similar across, but e-cigarettes still significantly different. So, again, they think that they're less likely to have the pharmacological and addictive effects if using e-cigarettes. And this is with or without nicotine. And part of the problem is, is that I think adolescents don't always recognize that e-cigarettes do contain nicotine.

And then, finally, social benefits. Here, if you look on the left, it's not 0-100% because the adolescents don't actually think that they're going to get benefits that much anyway, so we had to reduce the scale, otherwise you couldn't see it; 0-25% here. But what's interesting, with the exception of hookah, where they actually see a fair amount of benefit, which is, if you can't read in the back, look cool, look mature, or fit in.

Adolescents think, in general, e-cigs look cooler, but overall, the benefits are about the same, so the idea that they're going to get less harm but get about the same amount of benefits. So some really quick quotes from teens on the qualitative. "E-cigarettes are classy." "You can walk around with them." "They don't have any vapor." "No nicotine."

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That's what everybody is saying, no nicotine.

"People always tell you smoking's bad, and cigarettes and tobacco's bad, but if you take those out and you just smoke regular with just water, it's not bad" -- meaning the vapor. And "E-cigarettes - they're not worse than cigarettes, but they're more or less equal in how bad it is. So really not much difference...I don't really know that much about e-cigarettes."

And these qualitative data, by the way, are in press right now, in the *Journal of Adolescent Health*.

The other thing that I didn't bring, but I want to tell you because it has to do with my result, with my conclusions is also when we ask adolescents whether they're seeing messages, adolescents are seeing messages for the risks of cigarettes and the benefits of e-cigarettes, they're not seeing anything out there, yet, for the risks of e-cigarettes or obviously the benefits of cigarettes. So that's mostly what they're seeing.

So, in summary, adolescents believe that e-cigarettes are significantly less addictive and less risky to use socially and physically, followed by chew or hookah, cigarettes -- cigars and then cigarettes, with cigars and cigarettes being most similar; and smaller differences between cigarettes and

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e-cigarettes in the benefits. I didn't go into the age differences, but basically younger adolescents think that they're more harmful, and those who have engaged in the behavior think they're less.

So my last slide. In terms of implications, they really receive the messages that e-cigarettes are risky, but there is still work that needs to be done to adequately message on the risks related to e-cigarettes. Currently we have campaigns, great national campaigns, the TIPS campaign, FDA's Real Cost campaign that are focusing on cigarettes. They can and should be focusing on e-cigarettes. In California, the same thing. We're starting to get messages out there about e-cigarettes that we really need to do. And also clinicians, if you're clinicians in the audience, not just talking to youth about cigarettes but extending it to e-cigarettes. And, clearly, we need to regulate and restrict any messages that are perpetuating these misperceptions for adolescents.

Thank you.

(Applause.)

DR. DRESLER: Okay, our next speaker is Dr. Grace Kong and -- oops. I was just testing to see if you were ready. Okay, I'm sorry about that.

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The next speaker is actually Dr. Ashley Sanders-Jackson, and she's going to be speaking on Knowledge of E-cigarettes in Young Adults. Also from Stanford.

DR. SANDERS-JACKSON: So I appreciate you letting me call in. I did this work during my postdoctoral fellowship at the Stanford Prevention Research Center. It's funded by two grants, one of which Dr. Lisa Henriksen was the PI on, and the other which Dr. Christopher Gardner was the PI on.

Next slide.

So I really love Bonnie's work and admire all the work she does on adolescents and young adults. I'm particularly interested in young adults and e-cigarettes and actually other tobacco products, but I'm going to be talking about e-cigarettes today.

So there's some research that suggests that young adults 18 to 24 are maybe the most susceptible population to e-cigarette use, regardless of cigarette use status. There's a presentation by McMillan and colleagues at APHA. Young adults use e-cigarettes at higher rates than other groups already. In fact, 21% of young adults have ever tried e-cigarettes.

Next slide.

E-cigarettes or their vapor contain lots of interesting

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substances, including sometimes tobacco-specific nitrosamines, possible toxins in the flavoring, and some heavy metals.

Some state and local jurisdictions have recently implemented policies to restrict the use of e-cigarettes in smoke-free venues, impose excise taxes, or prohibited the sale of e-cigarettes to youth. North Dakota, New Jersey, and Utah, for example, are 100% vape free in smoke-free venues, except vape shops in Utah.

And e-cigarettes have been banned in a number of other contexts, including on airplanes and local trains in some places, like the Bay Area, the San Francisco Bay Area, and by the Maryland Transit Administration.

I put up this -- I'm sorry, we should be on Slide 3. Are we on Slide 3, where it says Back Off, Big Tobacco? Anyway, I put up this example because the city of San Francisco has a major anti-vaping campaign. And I know Bonnie was talking about the fact that there isn't a lot of -- there's a lot of good anti-tobacco information, but there's not, you know, a lot of information about e-cigarette constituents or some other information about e-cigarettes, so the public health community is providing about the risks and benefits.

Next slide.

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So there is a lot of e-cigarette marketing, and young adults seem to be a getting a lot of it. Jennifer Duke and colleagues, in a 2014 *Pediatrics* paper, found that based on a cumulative measure of exposure to, sort of, ads and television, 50% of all young adults 18 to 24 in U.S. television households were exposed to an average of 35 e-cigarette advertisements from October 2012 through September 2013. Young adult exposure to television e-cigarette advertisements increased 321% from 2011 to 2013, mostly from cable networks.

Of course, e-cigarettes are also marketed in lots of other contexts. For example, extensively online. Paek and colleagues, in a *Journal of Health Communication* paper in 2014, studied e-cigarette marketing on YouTube. Rachel Grana and Shu-Hong Zhu have also published work looking at websites and the content, the content of those websites in terms of e-cigarette marketing. They found lots of different types of claims, for example, that e-cigarettes can be smoked anywhere; that e-cigarettes are healthier than smoking; that e-cigarettes contain only harmless water vapor; that e-cigarettes are smoking cessation aids; they're novel.

Of course, there's also e-cigarette marketing in an off-line context. So, you know, a lot of us go to 7-Eleven or a

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tobacco retail outlet. You may also see advertisements for various types of e-cigarette products.

And so the next slide.

So I was working with a couple of people and we came up with some research questions that we wanted to think about in terms of e-cigarette marketing and e-cigarette information and what people know about it. So our big question is: What do young adults know about e-cigarettes? And we answered that in a couple of ways. Our next question is: How does this knowledge vary by demographics? So are there some groups that have sort of more knowledge or more uncertainty about what they know about e-cigarettes? The next question is: Is there an effect of marketing exposure on knowledge for e-cigarettes?

The next slide.

So our sample was data collected in March 2014, which was 1 month prior to the proposed FDA deeming, collected by GfK using addressed-based sampling, and the data was weighted to be representative, you know, an estimate of the sample. The sample is 1,247 18- to 34-year-olds. In terms of e-cigarette use, about 8% used e-cigarettes in the past 30 days. About 18% had used in the past 6 months, but not in the past 30 days. But 75% reported no use. In terms of combustible traditional

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cigarettes, about 11% of our young adults were former smokers, about 13% were non-daily smokers, and about 9% were daily smokers.

I wanted to talk a little bit about our marketing exposure variable. So our measure of marketing was, in the past 30 days, how often did you see advertisements for e-cigarettes? And then there were four possible locations: (a) when you went to a convenience store, liquor store, or gas station; (b) when you used social media such as Facebook, Twitter, or YouTube; (c) when watching television or cable shows; and (d) when reading newspapers or magazines.

Each item we asked people to respond on a 4-point scale. Don't know/never was coded as 0; once or twice was coded as 1; three or four times was coded as 2; and five times or more was coded 3.

As you can see, we have some diversity in terms of race. We had 54.4% non-Hispanic white, we had about 20% non-Hispanic black, and about 19% Hispanic. And some variety in terms of level of education.

The next slide.

This should be called "Knowledge" at the top. Our knowledge items. We had four response items. True, false,

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don't know, and refused were separate, although we collapsed them for the analysis, don't know and refused. There were very few refused.

We had two knowledge items about product constituents, the first of which was some e-cigarettes contain nicotine, and the correct answer to that is true. The second product constituent item was e-cigarettes do not contain any of the toxic chemicals that can be found in combustible cigarettes; the correct response is false. We had two regulation items: The federal government requires product safety testing for e-cigarettes, correct = false; and the federal government regulates e-cigarettes as smoking cessation aids, correct = true.

Next slide.

So just to give you sort of a general sense of what people know. In our young adult population, they seem to have a somewhat better understanding of whether or not e-cigarettes contain nicotine than the adolescents Bonnie talked about. As you can see, 57.3% of our sample knew that some e-cigarettes contained -- were correct that some e-cigarettes contain nicotine. However, 37% of our respondents responded "don't know" or "refused" to this item.

And, actually, the big take-home message from knowledge,

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if you look at the don't know/refused column which is highlighted in yellow, is that a lot of people felt that they didn't -- e-cigarettes, which is not surprising because they're new products, but there was also a substantial proportion of participants who responded incorrectly to do not contain toxic chemicals and that the federal government requires safety testing. So those were sort of the two things I wanted to highlight in terms of this.

Next slide.

One population that I think is particularly important is people who actually use e-cigarettes. So I want to orient you to this slide a little bit. The blue bar is people who have used e-cigarettes in the past 30 days. The sort of brownish bar is people who have ever used e-cigarettes but have not used in the past 30 days. And then the green bar is people who never used e-cigarettes. And so these are the proportions of each of those populations that had correct knowledge about e-cigarettes. And unsurprisingly, in terms of whether or not e-cigarettes contained nicotine, past month users were most likely to be accurate.

There's not a lot of variety in terms of e-cigarette use and whether or not things contained toxic chemicals.

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However, for the two regulatory items, current users were somewhat more likely to be correct than past users and never users. But the accuracy that people understand the regulatory environment is fairly poor.

Next slide.

So the analysis that I'm going to be talking very briefly about is multinomial logistic regression. The outcome is relative risk comparing "incorrect" or "don't know" to "correct." So "correct" is the reference category. Independent variables were e-cigarette use, smoking status, exposure to e-cigarette marketing, and sociodemographic variables.

Next slide.

First I'm going to be talking about product constituents. So I want to highlight a couple of findings. I know this is a lot of text, but if you can look just primarily at the things highlighted -- circled in orange, results suggest that compared with never users of e-cigarette, ever users (not in the past 30 days, but ever users) and current users (any use in the past 30 days) had a lower likelihood of responding that they did not know that some e-cigarettes contain nicotine. So they have a greater sense of certainty about whether or not e-cigarettes

contain nicotine. You may note that they also didn't tend to be more correct versus incorrect, which is the thing next to the orange circles.

Next slide.

Black non-Hispanics had a higher likelihood of being incorrect or responding "don't know" to both items about product knowledge. Other non-Hispanics and Hispanics had a higher likelihood of answering "don't know" or incorrectly about e-cigarettes containing some nicotine, but there were no ethnic differences on knowledge about toxic chemicals.

Next slide.

Reporting more frequent exposure to e-cigarette marketing was associated with a lower likelihood of responding "don't know" to knowledge items about nicotine and toxic chemicals. However, reporting more frequent exposure to e-cigarette marketing was also associated with a higher likelihood of responding incorrectly to an item about nicotine. So it may be that seeing more marketing makes people feel more certain.

Next slide.

In terms of regulation, current or past 30-day users of e-cigarettes were less likely to be incorrect about safety testing and being regulated as a cessation aid. They also had

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a lower likelihood of responding "don't know" versus being correct for the question about regulating e-cigarettes as a cessation aid.

Next slide.

Non-Hispanic blacks had a greater likelihood of responding "don't know" or incorrectly than non-Hispanic whites to both items about regulation. Other non-Hispanics were more likely to respond "don't know" to the item about e-cigarettes as a cessation aid.

Next slide. I promise, this is the last table.

Greater self-reported exposure to e-cigarette marketing was associated with a lower likelihood of responding "don't know" to the question about safety testing and regulation for cessation. So, again, the marketing may be providing people with a sense of certainty.

Next slide.

So many young adults don't know or have incorrect knowledge about e-cigarettes.

E-cigarette users were more likely to respond "don't know" to e-cigarettes contain nicotine. Perhaps this would suggest the need for labeling on packages.

Non-Hispanic blacks had a higher likelihood of responding

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"don't know" and incorrectly about e-cigarettes. I know that young adults, which really is this population, consumed e-cigarettes at slightly lower rates, but they certainly have been recipients of significant e-cigarette marketing. And so it seems like this knowledge gap may need to be remedied by informational intervention, the knowledge gap at the time of this data collection.

It's clear that e-cigarette marketing is serving as a source of information, both correct and incorrect. And so additional information from the public health community, as we develop an improved scientific basis for making decisions and claims about e-cigarettes, may increase accuracy of people's knowledge.

Next slide.

So I think there are some things that we really need to keep thinking about in terms of young adults and e-cigarettes, one of which is to track their changes and knowledge over time.

Unfortunately, this was not a longitudinal study. I think it's really important to understand, as the marketing and the regulatory environment evolve, for example, after the proposed deeming, as the deeming moves forward, as there's news about the deeming, as e-cigarette marketing continues to evolve, as

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new companies and organizations become involved in that process, what do people know and how is that changing?

I think if we're going to consider having warning labels on packaging, we need to use good science in testing them. I think that's always a bit challenging. And also I think we need to sort of start thinking about the structural features of e-cigarette marketing that may affect knowledge for e-cigarettes. So are there particular attributes of content in the e-cigarette marketing on television that is increasing or decreasing accuracy of information that people have?

Next slide.

This actually came out of a paper in *Nicotine and Tobacco Research* that I worked with a couple of wonderful collaborators on: Andy Tan, Cabral Bigman, and Lisa Henriksen. And so I wanted to thank them and to thank you all for listening to me.

DR. DRESLER: Thank you.

(Applause.)

DR. DRESLER: Okay, Dr. Kong now. So our next speaker is Dr. Grace Kong, Yale School of Medicine, speaking on Message Framing for Preventing Electronic Cigarette Use among Adolescents and Young Adults.

DR. KONG: Hello, good afternoon. My name is Grace Kong,

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and I am an associate research scientist at Yale. Today I will be discussing our research findings that examine the preference of framing e-cigarette prevention messages among adolescents and young adults.

First, I would like to acknowledge the grant funders and the research team. There was a picture of Dr. Krishnan-Sarin here, and now it's gone, but I'm glad that she gave a talk earlier because you met her in person. But the grant is funded -- she's the PI of the grant, Yale TCORS. And we have a research team here. The authors do not have any conflict of interest to report.

As many speakers already pointed out today, e-cigarette use rates among youth are very high. Our research group also found that many adolescents in Connecticut have seen an advertisement of e-cigarettes. So, for example, 70% of middle school and 61% of high school adolescents reported seeing e-cigarette advertisements in multiple locations, which includes billboards, social media, and TV.

To combat the heavy marketing of e-cigarettes in many venues, we need to develop powerful e-cigarette prevention messages. So our goal was to develop the content of e-cigarette prevention messages and determine if the framing of

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the messages could enhance the effectiveness of preventive messages as part of the effective health communication strategies that could be used in programs for adolescents and young adults.

Prevention message effectiveness may depend on appropriate framing of the messages. This is based on the Nobel Prize winning prospect theory developed by Tversky and Kahneman, and the basic tenet of the prospect theory is that the persuasiveness of the message is influenced by the manner in which the choices are framed. So, for example, gain-framed messages that maximizes the gains are more effective for preventing behaviors that have clear outcomes, like engaging in physical exercise. On the other hand, loss-framed messages that minimize the losses are more effective for preventing behaviors with riskier, less certain outcomes, for example, like disease detection.

The effectiveness on message framing on health behaviors have been examined a lot in the literature. In the smoking cessation literature, results show that among adults, gain-framed messages are more effective; however, among adolescents, loss-framed messages are more effective. And there are some sex differences. For example, women who perceive low risk of

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smoking prefer gain-framed smoking messages. On the other hand, women who perceive high risk of smoking, they prefer loss-framed smoking messages.

So, in terms of e-cigarette prevention messages, gain-framed messages would emphasize the benefits of not using e-cigarettes, and a loss-framed prevention message for e-cigarettes would emphasize the cost of using e-cigarettes. So, in our study, the first aim was to assess whether adolescents and young adults prefer loss- or gain-framed e-cigarette prevention messages. And our second aim was to assess whether the preference for loss- and gain-framed messages would differ by gender, race, e-cigarette use status, or cigarette-smoking status.

So, first, we developed the content of the prevention messages through the use of focus groups in middle, high school, and college students. And from those focus groups we identified 11 message domains that could be used in the prevention messages. And, of those, we selected four message themes that could be framed in terms of losses or gains. And based on those findings, we developed the messages, and we also tested it with college students to assess the appropriate wording and to see if the messages are appropriate. And based

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on that, we developed the messages and we included them in the surveys.

So, to assess the preference, we conducted school surveys in Connecticut, and the schools that were surveyed were represented in different district reference groups, and those groups are based on socioeconomic status, financial needs of the schools. All the study procedures were approved by the Yale IRB and the participating schools. So the middle school and the high schools, we obtained passive parental permission, and all participants were informed of the anonymity, voluntary nature of the survey, and the limits to confidentiality.

The schools that were surveyed were in the New Haven County area, and the total number of students surveyed was 5,405 students. And this consisted of four high schools, 3,614; two middle schools, 1,166; and one college, which is 625. The response rates of the surveys were high. In middle school it was 87%. I'm sorry, in high school it was 87%, and in middle school it was 94%. In college, we did not sample the entire school, but we selected random classes, and we administered surveys. So we don't have a response rate for the college students.

We assessed e-cigarette status by asking the question:

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Have you ever tried e-cigarettes? Those who indicated no were coded as never e-cigarette users, and those who indicated yes were coded as lifetime e-cigarette users. In our sample, the lifetime e-cigarette users was 21.4%.

We assessed cigarette-smoking status by asking the question: How old were you when you first tried a cigarette, even one or two puffs? Those who indicated "I never smoked" were coded as never cigarette smokers, and those who provided a valid age of onset were considered lifetime cigarette smokers, and the rate was 19.9%.

This shows demographic characteristics. The first column shows the total sample, and the second column shows lifetime e-cigarette users. And what you see here is that males were slightly more likely to be e-cigarette users. Sixty-eight percent were lifetime e-cigarette users who were white. Seventy-nine percent were high school students. This is because this is based on the entire sample of lifetime users, and there were more high school students, so the percentage is higher. I'd like to point out that 63% of lifetime e-cigarette users have also tried cigarettes.

The preference of messaging framing of an e-cigarette prevention message was assessed by asking the participant to

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choose, for each of the four themes, whether they prefer the loss- or the gain-framed message using the question, which message would you use to convince somebody your age not to use e-cigarettes?

The first theme was financial cost. The loss-framed financial cost message stated, "You spend more money if you use e-cigarettes." The gain-framed message for this theme was "You save money by not using e-cigarettes."

The second theme is health risk. The loss-framed health risk message is "You may be exposed to unknown health risks if you use e-cigarettes." The gain-framed health risk message is "You may avoid unknown health risks if you don't use e-cigarettes."

The third theme was addiction. The loss-framed message for this theme is "You may increase your chances of being addicted to other tobacco products if you use e-cigarettes." And gain-framed message is "You may lower your chances of being addicted to other tobacco products if you don't use e-cigarettes."

And, finally, the fourth theme was social label. The loss-framed was "People will label you as a smoker if you use e-cigarettes," and gain-framed message was that "People won't

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label you as a smoker if you don't use e-cigarettes."

We conducted descriptive statistics, and we conducted four separate logistic regression analyses for each of the four themes as a separate dependent variable. Independent variables for each of the models included:

- Age group (comparison between adolescents versus young adults)
- Biological sex (comparison between males and females)
- Race (whites versus non-white)
- E-cigarette use status (never users versus lifetime users)
- Cigarette-smoking status (never smokers versus lifetime cigarette smokers)

Bonferroni-adjusted p-values of less than 0.01 were considered statistically significant.

So this is the adjusted logistic regression models comparing loss- and gain-framed e-cigarette prevention messages. So each of the four columns represents the four different themes. And the first column here are the independent variables that I presented, and the yellow highlighted areas are statistically significant findings. And I'll walk you through this with charts so you don't have to pay

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too much attention to this table here.

What we find is that, overall, females are more likely to prefer loss-framed messages across all different four themes. And we found that young adults are more likely to prefer a loss-framed message when it comes to social label, compared to adolescents. And we also found that among never e-cigarette users, they prefer loss-framed messages when it comes to health risks and social image compared to ever lifetime e-cigarette users.

So this is showing the preference of message framing for the theme of financial cost, and what you find is that overall, people prefer a gain-framed message when it comes to financial cost. But we also found gender differences. The blue bar is males, and the green bar is females. And what it shows is that for males, they prefer a gain-framed message for financial cost, and for females, they prefer a loss-framed message for financial cost.

And this is a theme of health risk, and what you find is that, in the overall sample, they prefer a loss-framed message when it comes to health risk. But there is also a gender difference. What you find is that for females, they prefer a loss-framed message, and for males, they prefer a gain-framed

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message when it comes to health risk.

This is the theme of addiction. Similarly, in the overall sample, they prefer a loss-framed message, but also gender differences show that females prefer more loss-framed and males prefer more gain-framed. And the same with social label, where females prefer more loss-framed, and males prefer more gain-framed.

We also found differences with e-cigarette use status in the theme of health risk. What you find is that never e-cigarette users prefer a more loss-framed message, and ever lifetime e-cigarette users prefer a gain-framed message. And then with social label as well, we find a similar pattern where among never users, they prefer a loss-framed message, and e-cigarette lifetime users prefer a gain-framed message.

And we found one difference with the age groups, where the light purple is the adolescents and dark purple is the young adults. And what we find is that young adults prefer loss-framed, and adolescents prefer gain-framed when it comes to a social label prevention message.

So, in conclusion, developing effective public health campaigns regarding e-cigarettes is highly relevant to the FDA's plan to extend regulatory efforts toward e-cigarettes.

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And loss- and gain-framed messages may be used to enhance the appeal and effectiveness of the prevention messages. And what we find is that overall, loss-framed messages were preferred over gain-framed messages for themes related to health risk, addiction, and social label. And a gain-framed message was preferred over loss-framed messages in the themes related to financial cost or money. Also, the importance of gain- and loss-framed messages may vary depending on individual characteristics like gender, age group, and e-cigarette use status.

Thank you.

(Applause.)

DR. DRESLER: Thank you.

Our next speaker is Dr. Carla Berg from the Emory Winship Cancer Institute, speaking on the Overview of Recent Data Regarding Individual Perceptions of E-cigarettes, Flavors of Interest, and Reasons for Use or Discontinued Use.

DR. BERG: Thank you all for having me. I'll try not to be too redundant. A lot of the things that I found are pretty consistent with what some of my colleagues have already documented. So we'll just get started.

So my charge was to look at what beliefs or perceptions do

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e-cigarette users and nonusers have about the risks of e-cigarettes versus other tobacco products. And how do beliefs/perceptions vary across subgroups by age and by e-cigarette and other tobacco use. So I'm going to cover, in summary, as quickly as I can, three different studies. One examines interest in e-cigarettes versus smokeless tobacco products among smokers. The second is interest in flavors, reasons for use, and discontinued use in a young adult sample. And the third is perceptions of e-cigarettes versus other tobacco products and marijuana in young adults.

I do want to acknowledge my study team and my sources of funding: the NCI, the Georgia Cancer Coalition, and the CDC.

So the first study I'm going to talk about was conducted in the summer of 2013, and I got the dataset the day I got married. I don't know what I was more excited about, which is weird.

(Laughter.)

DR. BERG: And the objectives of this study were to examine, first, current smokers' interest in using or switching to e-cigarettes or smokeless tobacco for various reasons; and second, correlates of interest in these products; and, three, subgroups of current smokers in relation to interest in these

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products. And so this was a cross-sectional survey assessing sociodemographics, tobacco use, interest in e-cigarettes and smokeless tobacco among smokers, and knowledge about e-cigarettes among 2,501 U.S. adults recruited through an online consumer panel. And this was in *Nicotine and Tobacco Research* in 2014.

So smokers were about 40 years old, and there were 961 of them in our sample. We oversampled smokers. And it's 51% male, about 19% blacks, 71% white, and about 80% with more than a high school education. So slightly more educated than the U.S. population. This group smoked an average of about 22 days of the past 30 and about 11 cigarettes per day on smoking days, with 15% using menthol.

So, on average, we found that participants were more interested in using e-cigarettes versus smokeless tobacco across all the reasons provided. And I'll show the reasons that we provided them in the next slide. They were less interested in either product because of their potential use in places prohibiting smoking or due to curiosity, and more interested in reducing health risk or cigarette consumption or to aid in cessation.

This was interesting. About 28% believed that

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e-cigarettes were FDA-approved for cessation. And this was 39% of smokers who actually believed this. About 27% of smokers had talked with their healthcare provider about e-cigarettes, with about 18% reporting that their provider endorsed them for cessation. And we've done some qualitative interviews just this past year, asking healthcare providers about their clinical practices around this. And to be completely blunt, a lot of them told us that, you know, they would recommend them to their patients.

So here are the reasons that we provided them:

- Because you were in a place that didn't allow smoking
- To reduce your health risk
- To cut down on number of cigarettes you smoked
- To quit smoking
- Because you are curious or intrigued by the product

And then we gave them an overall interest score. And you can see that across every reason, there was more interest in using e-cigarettes versus smokeless tobacco, and there was also very high correlation and interest across the reasons and across the tobacco products. And I also note that, for being in a place where you couldn't smoke and that you were curious about the product, those two are rated as less important than

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the others.

So here are some correlates of interest in e-cigarettes.
So I'm going to try to focus more on the e-cigarette topic.

- Younger age
- Having children in the home
- Typically using menthol cigarettes
- Having made a quit attempt in the past year
- Talking to a healthcare provider about e-cigarettes
(regardless of the outcome of that interaction)
- Believing that e-cigarettes are approved by the FDA for
cessation

So then we did a cluster analysis using k-means, and it revealed three groups that were distinct in their interest in the products.

So the Moderates represented about 15% of current smokers, and they were moderately interested in using or switching to e-cigarettes or smokeless tobacco products across all reasons. So about a 4 to 6 on a 9-point scale. The Disinterested in Smokeless represented about 64%, and these were folks who were moderately interested in e-cigarettes (between 5 and 6 on a 9-point scale) but very low interest in smokeless tobacco. And then there were the Enthusiasts, which were about 21% of our

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cigarette smokers, and they had a high interest in both e-cigarettes and smokeless tobacco products, ranging from 7 to 8 on a 9-point scale.

To characterize these groups a little bit more, the Moderates were the least distinct of the three groups. I'll talk about the Disinterested so you can kind of see the extreme.

So the Disinterested in Smokeless tobacco, so this was people who were moderately interested in e-cigarettes but not at all in smokeless tobacco. They were the oldest of the three groups, and they were comprised of the greatest proportion of females, the smallest proportion of blacks, and the smallest proportion of those with at least a bachelor's degree. They had lower incomes, they were less likely to be employed, and they were the least likely to have children in the home. And in terms of their tobacco use behaviors, they smoked the most frequently and had the greatest cigarettes per day, were the least likely to use menthol cigarettes, and were the least likely to have made a quit attempt in the past year.

And then the Enthusiasts were actually the entire opposite of this category. So they were more educated, had lower smoking levels, and so on.

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So, in conclusion from this study, there was higher average interest in e-cigarettes, as we already have talked about. There was less interest in using these products, for some of the concerning reasons that we have. There were high rates of misbeliefs about the FDA approval of e-cigarettes. And healthcare providers are doing some things that, you know, we need to address. We need to give them some tools or some information to be able to deal with these interactions. And these findings may certainly inform educational campaigns.

The second study I'm going to talk about just briefly is not yet published, but it was presented at SRNT this past year, and the objectives were to examine preferred flavors and reasons for use and discontinued use of alternative tobacco products among users, former users, and nonusers. And we recruited 1,500 participants aged 18 to 34 through Facebook ads targeting tobacco users and nonusers in August 2014, and we assessed sociodemographics, tobacco use behaviors, flavors of interest, reasons for use and discontinued use. So our average age was about 25, and we had roughly an equal split of males and females. We were mostly white, about 87%, and about 13% Hispanic.

And I'll just give kind of the brief overview on this

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slide. About 56% of our group were current cigarette smokers. We had a lot of enthusiasm among the e-cigarette users on Facebook and the marijuana users. Our ads were really effective at recruiting those two samples. Smokeless tobacco, not so much. Cigars, not so much. But we had a lot of enthusiasm among those two groups, and I think probably because they're probably two of the most controversial topics.

And so this is just showing the flavors that folks were interested in, and this is both among users in each of the categories and nonusers. And some of the most popular ones are the fruit flavors across categories. And also candy flavors and caramel, vanilla, chocolate, cream flavors, and then menthol. And you can see that the users and the nonusers are pretty similar in terms of what they ranked to be the most appealing. And so this was -- they can check up to three that they would be interested in using or that they were currently using, depending on if they were users or nonusers.

And in terms of reasons for use of e-cigarettes, hookahs, small cigars, and smokeless tobacco, this is all among current users, and some of the major reasons for e-cigarette use were because they cost less, they were less harmful, they come in appealing flavors, they can help people quit smoking, they

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don't smell, they're more acceptable to nonsmokers, and they wanted to use them to quit smoking, and they like socializing with other users and they like experimenting with the flavors. So this flavor issue comes up, you know, pretty predominantly, particularly for e-cigarette use. Also hookah was another one where the flavors played a big part.

So this is reasons for discontinued use of e-cigarettes, hookah, and small cigars and smokeless tobacco among lifetime experimenters who are not current users. And one of the things that I'd like to point out is, for the same reasons that they were endorsed for use, they were also endorsed for discontinued use. So they were too expensive as opposed to less costly than other forms of tobacco.

And then one of the things that they also mentioned was that they didn't like the flavor, about 9% in the e-cigarette category and -- I feel like there's something missing in here. But, regardless, there are some interesting things in terms of the flavor. About 20% of people in the e-cigarette category said that they didn't like the flavors. So flavors and taste certainly play an important role in reasons for use and discontinued use among current and former tobacco users. Sweet flavors, particularly fruit flavors, are highly preferred among

current users and are of interest among nonusers. So regulating flavors of tobacco products may impact uptake and continued use by young adults.

And, finally, I'll just touch on another study that we've just launched, but some findings similar to this have also been published in *Substance Use and Misuse*. So this is our one funded by the FDA and NCI, and it is -- we call it Project DECOY, Documenting Experiences with Cigarettes and Other Tobacco products in Youth. And this is a college student-focused grant.

And our aims are to identify market segments of young adults attending colleges and universities in Georgia based on their psychographic profiles using market research methodology. I'm also working on my M.B.A. with a focus on marketing, and so I've been trying to leverage some of those skills toward our public health research. Our second aim is to examine the epidemiology of tobacco use among college student market segments over 2 years, including the sequencing of tobacco product use change and changes in some of the psychosocial sequelae associated with use; and then, finally, to investigate reasons for use of alternative tobacco products and how to best frame messages to alter attitudes about these products and

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regarding regulation.

So these are the schools. We have two public universities, two private universities, two technical colleges, and a historically black college, and we tried to get a good range in terms of urban and rural representation.

And this is a 2-year longitudinal study, and we have 3,418 participants. And at Wave 2, I'm happy to report, we have 87% retention. So we're enthusiastic about that. We did not anticipate to have good retention with our young adult samples, so we're thrilled. And these are just some of the measures that we included.

And this is just to highlight the different use profiles among the different tobacco products and marijuana within the sample. You'll see that whites and Hispanics are highly -- more represented in the cigarette product category. Little cigars and cigarillos, as we know, are more likely to be used among the black population. Smokeless tobacco also, as we know, more among our white sample. E-cigarettes, both for whites and for Hispanic, were more predominantly used. Hookah, more likely to be used among the black and Hispanic population. And then marijuana, about 22% of our black participants were using marijuana in the past 30 days.

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So this is the range of tobacco products in relation to how they are perceived to be used in the next year. So we asked them: How likely are you to use each of the following products in the next year? Ranging from 1 (not at all likely) to 7 (extremely likely). And so the most endorsed in terms of being likely to use in the next year was marijuana followed by hookah followed by e-cigarettes, although e-cigarette was not far from a lot of the other products.

In terms of perceived addictiveness of the different products, you'll see that, of course, cigarettes and smokeless tobacco were the most likely to be perceived as addictive, with marijuana and e-cigarettes and large cigars and hookah being less likely to be perceived as being addictive.

In terms of perceived harm to health, of course, again we see that cigarettes are off the charts, relatively speaking, and marijuana, hookah, and e-cigarettes are seen as being the least harmful. In terms of perceived social acceptability, we see that hookah, marijuana, and e-cigarettes are seen as being the most socially acceptable.

Perceived harm of the byproducts of these different products: So cigarettes were seen to have the most harmful byproducts, with marijuana and then e-cigarettes being

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perceived to have less harmful byproducts. And then we asked them about the likelihood of allowing people to use these products in their home, and they were most likely to allow e-cigarettes and then followed by hookah and marijuana.

And we included a range of different potential correlates of positive perceptions in our paper that's been published in *Substance Use and Misuse*, and that included friends' use of the range of tobacco products, parents' use of the range of the different tobacco products. And in that analysis, more positive perceptions of e-cigarettes -- and in this case we're just talking about less harmful to health, less addictive, and more socially acceptable -- included being male, parental use of combustible tobacco, friends' use of cigarettes, hookah, or e-cigarettes, and then one's own use of cigarettes.

So that study provided some information regarding the perceptions of the harm of the various tobacco products and addictiveness and social acceptability. Marijuana was generally perceived to be the least harmful, least addictive, and most socially acceptable.

But we really do need to document the reasons for these perceptions as well as the true nature of the health risks and addictiveness of e-cigarettes. I think we're trying to figure

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out what kind of messages we can give healthcare providers and, you know, our general population, and we really need to be able to come up with the evidence base to support whatever assertions we're making.

So at that, I'll just leave my future directions slide because I think I'm over time, and we'll move on.

(Applause.)

DR. DRESLER: Okay, our next speaker is Dr. Andy Tan from the Dana-Farber Cancer Institute and the Harvard T.H. Chan School for Public Health. He will be speaking on Is Exposure to E-cigarette Communication Associated with Perceived Harms of E-cigarette Secondhand Vapor?

DR. TAN: Hi, everyone. I'd like to thank the FDA for this invitation to share our research findings about public perceptions of harms of secondhand vapor and associations with exposure to e-cigarette communication.

I have no conflict of interests to disclose relevant to this presentation.

So a quick background about the context of this study. E-cigarette marketing. E-cigarette use is increasingly popular because of various relative advantages compared with smoking, including the apparent lack of harmful emissions. One

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potential source of information about secondhand vapors are e-cigarette marketing messages, which we have seen in earlier sessions. E-cigarette marketing frequently claims that vapors are harmless because they are just water vapor and not tobacco smoke.

These ads are also encouraging vaping in places where smoking is prohibited. Popular talk shows on TV have also featured e-cigarette use by celebrities who claim that e-cigarette vapors are safe. Claims by celebrities that secondhand vaping is just water vapor and that is, in the case of this David Letterman show, humidifying the space could be misleading and shape public perceptions about potential harms from breathing in secondhand vapors.

Some local and state health departments, including the State of Alaska and San Francisco, have launched public health campaigns to warn the public about potential harms of secondhand vapors from e-cigarettes. Here is a short clip of the Alaskan Health Department's TV campaign ad.

VIDEO: What's in e-cig cloud? Think it's harmless vapor? Think again. Nicotine. Ultra-fine particles that can lead to asthma, formaldehyde, lead that can cause brain damage, acetone found in nail polish remover. E-cigs, not harmless, not

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healthy. Don't let Big Tobacco cloud your judgment. Get the facts. AlaskaQuitLine.com.

DR. TAN: So these PSAs may provide information that counter the marketing and media messages about the relative harmlessness of e-cigarette vapor.

In addition, we are seeing that state regulations have been introduced to restrict vaping in public places. Three states across the U.S. have started to regulate e-cigarette use in smoke-free places, and these include New Jersey, North Dakota, and Utah.

As for local regulations or county regulations, as recent as in April 2015, the American Nonsmokers' Rights Foundation reported that there are 354 local laws restricting e-cigarette use in 100% smoke-free venues. These state and local laws further counter messages claiming that secondhand vapor is harmless.

Our overall research agenda involves studying the impact of e-cigarette communication from various sources on tobacco-related cognitions and ultimately on population outcomes, including the support for tobacco regulations and tobacco use behaviors. While earlier surveys have reported public perceptions of harms of people using e-cigarettes, there is

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currently a lack of data on public perceptions of harms to people who are exposed to secondhand vapor.

So the objectives in this study were to describe the perceived harms of secondhand vapor based on a national survey of U.S. adults, and to analyze whether exposure to e-cigarette communication through advertising, media (other than advertising), and interpersonal sources is associated with perceived harms of secondhand vapor.

So I'll walk you through the methods briefly. We collected online survey data among a representative sample of U.S. adults, 1,449 of them, between October and December 2013. And this was a sample through the GfK panel. To measure exposure to e-cigarette communication, we measured the frequency of exposure to advertising promoting e-cigarettes, the frequency of exposure to other media that talk about e-cigarettes, and the frequency of discussion with family or close friends about e-cigarettes in the preceding 30 days.

The response options ranged on a 4-point scale, and because e-cigarettes are such a novel product, we felt that it is important not only to measure the frequency of exposure but also how people perceived these communications to be positive, mixed, or negative. Therefore, we included a measure of

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valence in each form of communication, and this is defined here as whether the information is perceived to be positive, negative, or a mix of both.

Based on these respondents' responses to these measures, we categorized respondents into four groups: having no exposure in the past 30 days, which was the referent category; negative valence to each of these sources of exposure; a mix of positive and negative; and positive valence.

There were three items in a survey measuring perceived harms of vapors from e-cigarettes. The first item asked if respondents think that breathing vapors from other people's e-cigarettes is harmful to their health. And this ranged from "Not at all harmful" to "Very harmful to my health" on a 7-point scale.

The second asked how concerned they would be about the impact of breathing vapor from other people's e-cigarettes if they were regularly exposed. And this ranged from "Not at all concerned" to "Very concerned" on a 7-point scale.

And the third outcome that we measured was a comparative harm measure, asking people to compare if breathing secondhand vapor was less versus more harmful than secondhand smoke, on a 5-point scale.

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We utilized multiple regression models to predict each perceived harm item, and the analyses adjusted for various covariates. Sorry for the jumble over there. Analyses were weighted to match the sample to the U.S. adult population based on the most recent current population survey data.

So let me share with you the results from these analyses.

The mean age of the sample was 49.5 years. We had a good balance between male and female respondents. Most were non-Hispanic Caucasian, and about a third completed college education or higher. There was a slight under-representation of minorities and adults with lower education in this sample. Twelve percent have tried e-cigarettes in the past.

The participants' exposure to e-cigarette communication in the preceding 30 days was infrequent. The mean frequency of e-cigarette communication from these three different sources was between 1.3 to 1.6 on scales that ranged from 1 to 4. The majority of respondents who reported exposure to each of these three channels of e-cigarette communications perceived the valence of the information as positive.

Participants reported moderate perceived harms on health associated with breathing secondhand vapor and moderate concern about health impact of secondhand vapor. Overall, participants

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viewed inhaling secondhand vapor as less harmful than inhaling secondhand smoke. The mean of the comparative harm of secondhand vapor versus secondhand smoke was 2 on a scale ranging from 1 to 5.

So this is a slightly complicated figure, but I will walk you through this. So on the y-axis are the predicted perceived harms, adjusting for the various covariates that I mentioned earlier. So, in this chart, what we are seeing is that perceived negative valence of ad exposure and the interpersonal discussion was associated with higher perceived harm of breathing secondhand vapor. So that's the blue bar with the asterisks that you see for ads and interpersonal exposure. In addition, perceived positive valence of interpersonal discussion versus no exposure was associated with lower perceived harm. And this is the predicted concern of health impact of breathing in secondhand vapor by the valence of exposure across the three sources of communication.

Perceived negative valence of ads, other media, and interpersonal discussion versus having no exposure were all associated with higher concerns of health impact of breathing in secondhand vapor. In addition, perceived positive valence of interpersonal discussion versus no exposure was associated

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with lower perceived harm.

And the third chart is the predicted perceived comparative harm of breathing secondhand vapor to secondhand smoke by the valence of exposure, and we are seeing very similar patterns here. Perceived negative valence of ads and interpersonal discussion versus no exposure, the blue bars, were associated with higher perceived comparative harm of secondhand vapor versus secondhand smoke. And perceived positive valence of interpersonal discussion was associated with lower perceived comparative harm.

So, in summary, this study suggests that e-cigarette communications across different sources, especially from ads and interpersonal sources, could play a role in public perceptions of the harmfulness of secondhand vapor. Further research is necessary to monitor longitudinal trends in these public harm perceptions as evidence about the pollutants contained within secondhand vapor emerges.

We also need to examine how perceived harms about secondhand vapors might influence behaviors, including e-cigarette initiation and adoption, as well as policy opinions such as supporting vaping bans in public places.

Study limitations. The analyses were based on cross-

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sectional observational data. We relied on self-reported measures of exposure, which may be subject to memory or recall biases. And the study did not assess the impact of e-cigarette communication -- sorry -- the specific content of e-cigarette communication that participants were exposed to.

So some future directions leading from this. We are planning an online survey experiment to test e-cigarette marketing effects on risk perceptions and policy support among young adults; a smoking lab experiment bringing in young adults to a smoking lab to test the effects of exposures to e-cigarette ads on vaping cues and cravings and smoking behavior; and evaluating the impact of different formats of product ingredient labeling and warning labels on risk perceptions among e-cigarette users.

The data for this analysis came from the Annenberg National Health Communication Survey, which is supported by the University of Pennsylvania and the University of Southern California.

I would like to acknowledge my esteemed collaborators, Cabral Bigman, Sue Mello, and Ashley Sanders-Jackson, for this work. And the paper is available publicly on *BMJ Open*, and I'm happy to share a copy, if you'd like.

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Thank you.

(Applause.)

DR. DRESLER: So if we could have the speakers come up, please, for the panel discussion.

So, for our transcriber, it will be Drs. Berg, Halpern-Felsher, Dr. Kong, Dr. Peters. And there's an empty space there for Dr. Ashley Sanders-Jackson on the phone, and Dr. Tan at the end, okay?

So a couple of clarifying questions to start off with. Dr. Berg, you had talked about byproducts. What are byproducts?

(Off microphone comment.)

DR. DRESLER: Oh, yes, I'm sorry. I forgot. Thank you very much.

Dr. Peters, if you'll introduce yourself, please, and your declaration of interests.

DR. PETERS: My name is Erica Peters. I am a principal research scientist at the Battelle Public Health Center for Tobacco Research, and I have no conflicts to declare.

Thank you.

DR. DRESLER: Thank you.

Okay, Dr. Berg, what are byproducts?

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DR. BERG: No, I did not use that term when I presented the information to the participants.

DR. DRESLER: Okay.

DR. BERG: So we said smoke or vapor resulting from the use of the following products.

DR. DRESLER: Oh, okay. All right, thank you. So it is smoking vapor. So that was my next clarifying question.

And this was for Dr. Tan. So, you know, a couple of things: People are saying that physicians are recommending the electronic cigarettes to their patients to help them with smoking. I think 18% was in one of the presentations. And then you had vapor and SHV. But isn't e-cigarette smoke, isn't it an aerosol and not a vapor? And so that's why I'm wondering, when we're starting to communicate, especially to our hopefully educated colleagues, would we be using aerosol or vapor when we communicate with them?

DR. TAN: Well, at a point in time of conducting of this survey, vapor was frequently used a lot in the news coverage as well as in the advertising media, which was why we utilized that word. I think the term aerosol is a much more recent use of describing emissions from secondhand -- from e-cigarette use. So I think in future research we should work to what's

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using emissions or the new term that you mentioned.

DR. DRESLER: Yeah, I was just wondering that because I think most people use vapors. You know, vape shops. We heard that Vapefest was a new word --

DR. TAN: Correct.

DR. DRESLER: -- for me. But I'm always thinking, you know, as we're speaking -- as a physician also, you know, that it's not a vapor, that it is an aerosol, and I start thinking of SHV. That was the first time that I had seen that. So that's secondhand --

DR. TAN: Vapor.

DR. DRESLER: Yeah. So SHV/SHA.

Okay, questions coming in. So okay, Dr. Tan, so we'll stay with you. What are the known and verifiable harms of e-cig and secondhand -- it says vapor, but I'm going to use aerosol, okay? So secondhand aerosol beyond, what, speculative risk. Do we not risk the credibility of public health if warnings are put out on PSA messages before it is established by actual science?

DR. TAN: I think we're going to hear more about that tomorrow, right? So I'm going to defer that to the toxicology --

DR. DRESLER: Okay.

DR. TAN: -- experts who will be presenting tomorrow.

DR. DRESLER: Okay.

DR. TAN: Yeah.

DR. DRESLER: Okay, that's fair.

DR. TAN: I'm sure there's exciting evidence that you'll be presenting.

DR. DRESLER: Okay.

DR. TAN: So I don't want to jump your gun.

DR. DRESLER: I think what the person was getting at is should we wait until we have the actual evidence in before we communicate? And I think, as we've learned, there's already so much information that's out there already, so how do we start?

Does anybody else want to address that?

DR. HALPERN-FELSHER: If I'm understanding correctly what you're saying -- I currently am the PI of a project in California. I'm also developing school-based interventions and curricula around e-cigarettes and other tobacco products, and we had the same question. And basically what the Department of Public Health and the California Department of Education disclosure is saying is we need something, because like the data, I was saying, youth are getting the perceptions

regardless.

So while we don't know it all, we certainly know enough, I think, to be able to start making some statements. We certainly know enough about nicotine, and we know some of the facts that they're still misperceiving. So I think to stay silent just perpetuates some of the misperceptions that are going on out there.

So, you know, if we don't say anything, that's wrong. And I think we have qualifiers. But I think, again, there's enough out there that we can start developing interventions and better messages than we have now.

DR. DRESLER: Anybody else?

DR. BERG: I guess I would just add to that. You know, we need to be at least highlighting -- and we can't even say there are misperceptions or anything necessarily, but we need to be highlighting that a lot of the media and a lot of the advertising that they're getting is unfounded, too. So even though we don't know everything yet, we do know that the industry also doesn't know yet. So I think that's what we need to be making sure, that the messages -- that there's gaps in the knowledge. So any assertions that are being made about the relative safety should be taken with a grain of salt.

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DR. DRESLER: Okay.

DR. KONG: I think when it comes to teens, just because it's marketed and just because it's sold, people might believe that whatever is out there is safe to use. So even getting information out there that we don't know about e-cigarette, the health effects of it, is important for adolescent users.

DR. DRESLER: Okay. Dr. Sanders-Jackson, I don't want to forget about you. So if you're on the phone, if you have any comment. You don't have to, but if you -- I just don't want to forget about you on the phone.

(No audible response.)

DR. DRESLER: Okay. You might be on mute, too, so sometimes I do that. So just jump in there if you want to respond.

So the research seems to show that most people correctly understand the low risk, but a few grossly overestimate them. Which of these do you consider to be a bad thing? So the low risk of e-cigarettes, but some of them grossly overestimate the risk of them. So how would you respond to that? I think it's pretty similar to what we just went through before, you know, waiting for the evidence. Comments?

DR. PETERS: I don't think we know enough yet to be able

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to say anything definitively.

DR. DRESLER: Okay.

DR. HALPERN-FELSHER: This is something, and I don't know if this was referring to some of the data I show where certainly the perceptions of risk were pretty high. It's a function of the measure. We can get into a whole day of -- which we're going to next week, in fact -- how do we measure risk perceptions? But really, if you're looking in within-subject and looking at comparisons across, regardless of if they're saying it's 80% or 20% or whatever, if you compare, then you're still seeing differences in perceptions based on product.

So I think that may be what the person is getting at. And I get that a lot with, well, even though they perceive lower risk, they're still seeing a lot of risk, and isn't that a good message? No, not if those lower perceptions translate into behavior.

DR. DRESLER: Okay. What are the critical gaps in understanding consumer understanding of e-cigarettes? So what are the critical gaps? So we've heard pro and con, and we've been addressing that, you know, we don't have enough of the science, but there's a lot of advertising out there and a lot

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of perceptions. What are the gaps?

DR. BERG: Well, I guess one thing is that people don't -- the general consumer probably doesn't understand this issue of regulation, right? And so I guess in some ways communicating what things in the world get regulated, dog food, you know, whatever, and making sure that it's known that this is kind of standard and that there isn't a regulation around e-cigarettes as of now. And just from the standpoint of consumer safety, you know, consumers need to know that there's generally not regulation of whatever product they're putting into their body, and like I said, maybe comparing that to other things that they may not realize are being regulated.

DR. DRESLER: How about let's revise that question?

Go ahead.

DR. TAN: I think there's also a critical gap in public understanding about the issues of e-cigarette use, secondhand vapors, and things like that, and more specifically, what uncertainty and controversy and conflicting information that the public is being exposed to might have some kind of impact on their risk perceptions, their use of the product, and ultimately support or opposition to ongoing regulatory efforts either at the federal level or the state or the county level.

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So we don't yet know whether this uncertainty and conflicting information environment is helpful or harmful on public perceptions, policy support, and other outcomes. So I think that needs to be addressed.

DR. DRESLER: Okay. You're a physician, also. Let me -- because one of the things I was thinking -- we were talking about adolescents and adults, but also physicians. Any recommendations for how we help our physicians and the recommendations that they are giving to their patients?

DR. TAN: I think on the Memorial Sloan Kettering Cancer Center's website, there is a frequently asked question that is available for healthcare providers in the oncology setting. Perhaps that could be made more general for primary care providers, pediatricians, and other healthcare providers.

DR. PETERS: I think another gap is how special populations -- you know, how they perceive e-cigarette products. So a lot of the talks that we just heard were about adolescents' and young adults' perceptions, and certainly, those would be a special population of e-cigarette users. But I think we really lack data on other special populations.

So we recently completed a survey of adults in outpatient substance abuse treatment, which I think would qualify as a

special population, and we examined their attitudes and knowledge and beliefs about e-cigarette use. And one thing that we found concerning was that about 30% of our sample said that they thought that e-cigarettes could help them stop their drug and alcohol use, and we have no idea why they thought that. We definitely want to explore that further. We don't know how successful they may have been in terms of their e-cigarettes helping them stop their drug or alcohol use, but that was something that came up for us, you know, this issue of how special populations may differ in their attitudes about e-cigarettes.

DR. DRESLER: That's interesting.

Okay, in the absence of more certainty about health effects, how do we determine how accurate the understanding is? So if we don't know the answer, we don't have complete evidence, how do we know how good the understanding is?

DR. BERG: Yeah, I guess that's one thing that, you know, my future direction slide -- we need an evidence base to be able to communicate just that. And I mean, I think right now we're trying to -- the best we've got is to be able to say we don't know yet and combat, like, the assertions that the industry or those folks coming up with the marketing do know.

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But, yeah, that's definitely like square one. We can't move drastically further down the road until we have some good evidence.

DR. DRESLER: So I'm going to push on that one. So what do you do? You're a physician; we have 18% saying use it. So, you know, the physician that's sitting and, you know, talking to a patient --

DR. HALPERN-FELSHER: So I think, going back to what we said a few minutes ago, there are some things we do know. Nicotine. It's not just water vapor. There's aerosol. What is in there, the chemicals that are in there? We may not know 5-year risk, 1- or 2-year risk, 20-year risk. We certainly don't know in terms of cancer. But there are things that we do know. And for adolescents, young adults, special populations, whatever, to keep recapitulating vapor, no nicotine, totally harmless is wrong. You know, we can't quantify, but we certainly have some truths.

Right now I'm in the division of adolescent medicine. I got my group to talk about e-cigarettes with youth just by simply saying, you know, are you using them, what do you think is in them, let's discuss the different products, let's talk about the fact that they're not just water. Even just that, I

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think, is going a lot farther than what we're doing right now. And that's what we're doing in our e-cigarette -- we're talking about nicotine, we're talking about flavorings and potential harm in the intervention that we're developing. So even in the absence of information, like I said, there's still stuff we can say, and we should.

DR. DRESLER: And perhaps about dual use?

DR. HALPERN-FELSHER: Absolutely about dual use and about cessation. I didn't show all the qualitative data that we have, but a lot of people are learning the information, the young people, from their parents who are using it as a cessation device. And so they're saying it must be fine if my parents are using it.

And so they're not even -- even if we did a harm -- I'm not pro harm reduction, but even if we did that, you know, right now they're just saying it must be fine because mom and dad are using it. So that's where they're getting their information is from them or from peers. And we haven't even thought about, you know, if they're using other products other than nicotine or tobacco and marijuana and things like that.

DR. DRESLER: Okay. How confident are researchers about the accuracy of participant recall of exposure to e-cig ads and

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communication and the media? So you're asking them recall. How confident are you in their ability to make that recall? Somebody has got to answer that because we've been hearing about it a lot.

DR. PETERS: I think it depends on the period of time that the recall is over. Asking someone to recall something that happened yesterday is likely more accurate than asking them to recall something that happened in the past 6 months. Certainly it would be better if we could have research that tracked people over time prospectively and ask them at the end of each day, you know, specific questions about what types of ads they were exposed to. I don't know if we have that yet, but that would be the most ideal scenario.

DR. DRESLER: Dr. Tan.

DR. TAN: I wouldn't suggest throwing out self-reported exposure measures altogether. There are multiple studies in the past that have tried to validate self-reported recall to advertising, to PSAs, to health campaigns, with actual GRPs or advice of health campaigns, and if they have found a significant correlation between self-reports and actual advice. So I wouldn't throw that out right away.

DR. KONG: I would also like to add that a lot of

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advertisements, they work through implicit association. So the previous speaker on the previous round had talked about implicit measures of some of this advertising exposure. So I think that's something to kind of consider as well. It doesn't have to be explicit memory recall, but it does affect your thinking and your behavior in certain ways.

DR. DRESLER: Right. Okay, given the prevalence of poly-use, how important is it for messaging to address multiple products versus focusing on specific products in isolation? So I think this is getting at the public health information campaign of looking at poly-use versus just talking about e-cigs.

DR. BERG: So I just recently saw a presentation by a colleague where they were looking at the characteristics of poly-users versus dual users versus single product users. And the poly-users are an interesting group because they're using kind of everything in the kitchen sink. And the people who are dual users were more likely to be using e-cigarettes and their other product, and they also had some data about their tobacco use history and sociodemographics that might suggest that they are using e-cigs as a harm reduction or cessation strategy.

So I think the question about intention of using these

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different products is really important in helping to inform the campaigns, and I think a couple of other presenters really highlighted that well. I mean, we need to know more about why people are using it and being able to target our messaging campaigns in various ways so that we're catching different segments of the population so that we can have impact.

DR. DRESLER: Yeah, go ahead.

DR. HALPERN-FELSHER: And I would say, you know, getting back to what we were saying earlier, in terms of what a physician says or what interventions say, you know, I think there we definitely also need to address it and that we know -- I don't have hard data yet, but in looking at this, that -- okay.

(Microphone malfunction.)

DR. HALPERN-FELSHER: Is it back? All right, good. I was worried that somebody from above didn't want me to say anything.

(Laughter.)

DR. HALPERN-FELSHER: So, you know, getting youth there, we don't have a lot of data on poly-use yet. I know we've collected and haven't analyzed, and it sounds like a lot of people as well. But just talking to youth and in terms of some

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of the qualitative, youth are using multiple products, and listen to young adults and they're choosing to use certain products in certain venues, like e-cigarettes were being used in the classroom because teachers, until recently -- and even some of the people in our studies say even now teachers don't know what it smells like or looks like, and so it's hard to protect.

So I think even there we need to really -- one is educate teachers and other authorities about different products that may be used by young people and adults as well, but also for interventionists and healthcare providers to have these conversations that, you know, if you're reducing your cigarette use to just a few cigarettes a day, it's still harmful and you're replacing it by -- still replacing it with nicotine. So just this idea of what dual use means, the potential -- we don't even know what the effects are, but the fact that you're not reducing your harm by using five cigarettes a day and then vaping all day or using aerosol all day. So I think we need to raise it.

DR. DRESLER: Okay. To what extent are perceptions of harm related to the fact that e-cigarettes are not combusted? So we've heard that much today, right? It's the combusted

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products that are the dangerous ones. So to what extent are perceptions of harm related to the fact that e-cigarettes are not? So people are thinking, well, they're not combusted, so they must not be harmful.

DR. HALPERN-FELSHER: I think that goes to what we don't know. We don't ask that specific question in our risk perceptions. That's a good question.

DR. BERG: I guess I would also wonder how -- you know, when we are asking about marijuana, is the first thing that comes to mind for them, combusted marijuana, because they're perceiving marijuana to be relatively safe, too. So I guess, yeah, definitely under the category of things we don't know, but -- yeah.

DR. DRESLER: Because I think Colorado is showing that a lot of the marijuana is ingested versus inhaled, too. So it's interesting.

Dr. Tan, did you have -- was that -- I didn't see you on there.

(Off microphone response.)

DR. DRESLER: Okay.

DR. HALPERN-FELSHER: Sorry. Can I answer that --

DR. DRESLER: Absolutely.

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DR. HALPERN-FELSHER: -- really quickly? Sorry. In our qualitative data that we have, that I showed you a little bit, young people don't like combusted marijuana rolled in paper, not because of harm differences, but they're telling us -- a small study -- they're telling us that it's too much like a combustible cigarette in that they're just not socially normative anymore and they're not okay to be using cigarettes.

And so they're equating the rolled tobacco -- excuse me, the rolled marijuana in paper to just be not cool because it looks like a cigarette. It's not so much the harm; it's more the social norms and the effects. So that may be part of what's going on, but again we don't know quantitatively yet.

DR. DRESLER: Okay. Dr. Halpern-Felsher and others have suggested that adolescents under-appreciate risk of e-cigarette use, and better messaging is needed. However, some data suggests adolescents rate risk of e-cigarettes fairly high, closer to cigarettes, than never use. Could you comment on if this means adolescents do perceive or overestimate risk of use?

DR. HALPERN-FELSHER: That they perceive the risks of e-cigarettes similar to cigarettes?

DR. DRESLER: So do adolescents perceive or overestimate risk of use? So I think that's what they're saying, is that

adolescents rate risk of e-cigarettes fairly high, closer to cigarettes.

DR. HALPERN-FELSHER: So our data don't show that it's closer to cigarettes. It's significantly less. What you're seeing close to each other is cigars and cigarettes, so the combustibles. But again it comes back to the measurement question that somebody had asked earlier, which is yeah, our percentages are high in general, but it's relative to each other. And that's a function of the measure itself, of the 0-100% scale. But even though they're rating them high, they're rating the risks of other products higher and e-cigarettes lower. So I'm not sure where the missing piece came in.

DR. DRESLER: Okay. Any other comments? I don't have more questions. Are there more questions in the room? No? No? Okay. Any comments? No further --

DR. PETERS: I have one question, actually, for Dr. Berg. I was very interested in your research on e-cigarette and marijuana-related perceptions. Are you asking any of your participants if they add THC oil to their e-cigarettes and what they expect from the high they get from marijuana and the effect from any nicotine that may be in the e-cigarettes?

DR. BERG: You are very timely. Yeah, so in the context of our longitudinal study, we're asking all the marijuana users have they ever used and then how they most frequently use. And so we've got a range of different ways they potentially could use it. So vaporized with or without tobacco. So we delineate all of that. And then we also created a skip section for people who were concurrent marijuana and tobacco users. And so we've got a range of items related to reasons for concurrent use.

And then we'll also get an opportunity in our qualitative interviews this summer to talk more about that. And one of my Ph.D. students, Jillian Shower, she's also got some qualitative interviews where she did like a two-by-two matrix of high versus low tobacco users and high versus low marijuana users and asked a lot about, kind of, the nuances of how they use, both in terms of sequencing and then also in terms of device and delivery.

DR. KONG: So we actually have some data on -- so we asked adolescents whether they use e-cigarettes to vape marijuana product, like wax plugs, and we found about 28% have used e-cigarettes to use marijuana.

DR. DRESLER: Boy, we're going to finish the workshop on

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that.

(Laughter.)

DR. BERG: On a high, so to speak.

(Laughter.)

DR. DRESLER: I actually would love to finish on that. So I can't top that one at all. I can't go any higher, either. So if we have no more questions and we all hear the thunder and I think we've heard the weather forecast, so we'll call it in for today. Thank you very much for the speakers and the panelists for today.

(Applause.)

DR. DRESLER: And tomorrow morning at 8 o'clock we start. So please come back tomorrow. And thank you to everybody today for their presentations, and the panel.

(Whereupon, at 4:28 p.m., the meeting was adjourned, to be reconvened the next day, Tuesday, June 2, 2015, at 8:00 a.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the
matter of:

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A PUBLIC WORKSHOP

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were held as herein appears, and that this is the original
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CATHY BELKA

Official Reporter

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